This Schedule is also available on the internet at
www.pbs.gov.au

EFFECTIVE
1 April 2015 – 30 April 2015

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

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These changes to the Schedule of Pharmaceutical Benefits are effective from 1 April 2015. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2015 and are included, where applicable, in prices published in the Schedule —

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<thead>
<tr>
<th>Dispensing Fees:</th>
<th>Ready-prepared</th>
<th>$6.76</th>
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<tbody>
<tr>
<td></td>
<td>Dangerous drug fee</td>
<td>$2.71</td>
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<tr>
<td></td>
<td>Extemporaneously-prepared</td>
<td>$8.80</td>
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<td></td>
<td>Allowable additional patient charge*</td>
<td>$4.27</td>
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<th>Additional Fees (for safety net prices):</th>
<th>Ready-prepared</th>
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<tr>
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<td>Extemporaneously-prepared</td>
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<th>Patient Co-payments:</th>
<th>General</th>
<th>$37.70</th>
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<tr>
<td></td>
<td>Concessional</td>
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<tr>
<th>Safety Net Thresholds:</th>
<th>General</th>
<th>$1453.90</th>
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<tbody>
<tr>
<td></td>
<td>Concessional</td>
<td>$366.00</td>
</tr>
</tbody>
</table>

| Safety Net Card Issue Fee: | $9.47 |

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

Prescriber Bag

Additions

Addition – Item
10244E DIPHTHERIA TOXOID + TETANUS TOXOID, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials (MassBiologics tetanus and diphtheria toxoids adsorbed)
10251M OXYTOCIN, oxytocin 10 international units/mL injection, 5 x 1 mL ampoules (Oxytocin Sandoz)

Deletions

Deletion – Item
3491R TERBUTALINE, terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules (Bricanyl)

Alterations

Alteration – Maximum Quantity
3486L BENZYLPCINICILLIN, benzylpenicillin 600 mg injection, 1 x 600 mg vial (BenPen)  From 10 To 5

General Pharmaceutical Benefits

Additions

Addition – Item
10238W CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia)
10234P DESVENLAFAXINE, desvenlafaxine 50 mg tablet: modified release, 28 tablets (Desvenlafaxine GH XR)
10241B DESVENLAFAXINE, desvenlafaxine 50 mg tablet: modified release, 28 tablets (Desvenlafaxine Actavis)
10231L DESVENLAFAXINE, desvenlafaxine 100 mg tablet: modified release, 28 tablets (Desvenlafaxine Actavis)
10245F DESVENLAFAXINE, desvenlafaxine 100 mg tablet: modified release, 28 tablets (Desvenlafaxine GH XR)
10229J IRON SUCROSE, iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules (Venofer)
10254Q MESALAZINE, mesalazine 4 g granules: modified release, 30 sachets (Pentasa)
10226F SORAFENIB, sorafenib 200 mg tablet, 60 (Nexavar)
10242C SORAFENIB, sorafenib 200 mg tablet, 60 (Nexavar)
10250L SUCROFERRIC OXYHYDROXIDE, iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90 (Velphoro)

Addition – Brand
9012H APO-Alendronate Plus D3 70 mg/70 mcg, TX – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
9012H Alendronate D3 70 mg/70 microgram, UA – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
9183H APO-Alendronate Plus D3 70 mg/140 mcg, TX – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
9183H Alendronate D3 70 mg/140 mcg, TX – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
9351E Alendronate Plus D3 Calcium Actavis, GN – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
9351E Alendronate Plus D3 and Calcium Sandoz, SZ – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
9351E ReddyMax Plus D-Cal, RZ – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

2600W APO-Allopurinol, TX – ALLOPURINOL, allopurinol 100 mg tablet, 200
2600C APO-Allopurinol, TX – ALLOPURINOL, allopurinol 300 mg tablet, 60
2343H Amiodarone Actavis, GN – AMIODARONE, amiodarone hydrochloride 200 mg tablet, 30
2417F APO-Amitriptyline 10, TX – AMITRIPTYLINE, amitriptyline hydrochloride 10 mg tablet, 50
2417F Chem mart Amitriptyline, CH – AMITRIPTYLINE, amitriptyline hydrochloride 10 mg tablet, 50
2417F Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE, amitriptyline hydrochloride 10 mg tablet, 50
2418G APO-Amitriptyline 25, TX – AMITRIPTYLINE, amitriptyline hydrochloride 25 mg tablet, 50
2418G Chem mart Amitriptyline, CH – AMITRIPTYLINE, amitriptyline hydrochloride 25 mg tablet, 50
2418G Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE, amitriptyline hydrochloride 25 mg tablet, 50
2429W APO-Amitriptyline 50, TX – AMITRIPTYLINE, amitriptyline hydrochloride 50 mg tablet, 50
2429W Chem mart Amitriptyline, CH – AMITRIPTYLINE, amitriptyline hydrochloride 50 mg tablet, 50
2429W Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE, amitriptyline hydrochloride 50 mg tablet, 50
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<tr>
<td>2751T</td>
<td>Amlodipine AN, EA – AMLODIPINE, amlodipine 5 mg tablet, 30</td>
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<tr>
<td>2752W</td>
<td>Amlodipine AN, EA – AMLODIPINE, amlodipine 10 mg tablet, 30</td>
</tr>
<tr>
<td>1892N</td>
<td>APO-Amoxyccillin and Clavulanic Acid 125/31.25, TX – AMOXYCILLIN + CLAVULANIC ACID, amoxyccillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL</td>
</tr>
<tr>
<td>5009P</td>
<td>APO-Amoxyccillin and Clavulanic Acid 125/31.25, TX – AMOXYCILLIN + CLAVULANIC ACID, amoxyccillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL (Dental)</td>
</tr>
<tr>
<td>5011R</td>
<td>APO-Amoxyccillin and Clavulanic Acid 400/57, TX – AMOXYCILLIN + CLAVULANIC ACID, amoxyccillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL (Dental)</td>
</tr>
<tr>
<td>8319W</td>
<td>APO-Amoxyccillin and Clavulanic Acid 400/57, TX – AMOXYCILLIN + CLAVULANIC ACID, amoxyccillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL</td>
</tr>
<tr>
<td>8213G</td>
<td>Blooms the Chemist Atorvastatin, IB – ATORVASTATIN, atorvastatin 10 mg tablet, 30</td>
</tr>
<tr>
<td>9230T</td>
<td>Blooms the Chemist Atorvastatin, IB – ATORVASTATIN, atorvastatin 10 mg tablet, 30</td>
</tr>
<tr>
<td>2730Q</td>
<td>Terry White Chemists Baclofen, TW – BACLOFEN, baclofen 25 mg tablet, 100</td>
</tr>
<tr>
<td>8220P</td>
<td>Citalopram Actavis, VN – CITALOPRAM, citalopram 20 mg tablet, 28</td>
</tr>
<tr>
<td>5541P</td>
<td>Trusamide, QA – DORZOLAMIDE, dorzolamide 2% (20 mg/mL) eye drops, 5 mL (Optometrical)</td>
</tr>
<tr>
<td>8488R</td>
<td>Trusamide, QA – DORZOLAMIDE, dorzolamide 2% (20 mg/mL) eye drops, 5 mL</td>
</tr>
<tr>
<td>2373X</td>
<td>Herron ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
</tr>
<tr>
<td>8228C</td>
<td>Ikotab, QA – NICORANDIL, nicorandil 10 mg tablet, 60</td>
</tr>
<tr>
<td>8229D</td>
<td>Ikotab, QA – NICORANDIL, nicorandil 20 mg tablet, 60</td>
</tr>
<tr>
<td>3050M</td>
<td>Blooms the Chemist Perindopril, IB – PERINDOPRIL, perindopril erbumine 2 mg tablet, 30</td>
</tr>
<tr>
<td>3051N</td>
<td>Blooms the Chemist Perindopril, IB – PERINDOPRIL, perindopril erbumine 4 mg tablet, 30</td>
</tr>
<tr>
<td>8704D</td>
<td>Blooms the Chemist Perindopril, IB – PERINDOPRIL, perindopril erbumine 8 mg tablet, 30</td>
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<tr>
<td>8363E</td>
<td>Raloxifene AN, EA – RALOXIFENE, raloxifene hydrochloride 60 mg tablet, 28</td>
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<tr>
<td>1316G</td>
<td>Ramipril Winthrop, WA – RAMIPRIL, ramipril 10 mg tablet, 30</td>
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<tr>
<td>1977C</td>
<td>Ranitidine GH, GQ – RANITIDINE, ranitidine 300 mg tablet, 30</td>
</tr>
<tr>
<td>1849H</td>
<td>Iptam, AL – SUMATRIPTAN, sumatriptan 50 mg tablet, 4</td>
</tr>
<tr>
<td>8144P</td>
<td>Iptam, AL – SUMATRIPTAN, SUMATRIPTAN Tablet 50 mg (as succinate), 2</td>
</tr>
<tr>
<td>8448P</td>
<td>Ursosan, BZ – URSODEOXYCHOLIC ACID, ursodeoxycholic acid 250 mg capsule, 100</td>
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**Addition – Equivalence Indicator**

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<th>Code</th>
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<tr>
<td>2417F</td>
<td>Endep 10, AF – AMITRIPTYLLINE, amitriptyline hydrochloride 10 mg tablet, 50</td>
</tr>
<tr>
<td>2418G</td>
<td>Endep 25, AF – AMITRIPTYLLINE, amitriptyline hydrochloride 25 mg tablet, 50</td>
</tr>
<tr>
<td>2429W</td>
<td>Endep 50, AF – AMITRIPTYLLINE, amitriptyline hydrochloride 50 mg tablet, 50</td>
</tr>
<tr>
<td>9365Y</td>
<td>Pristiq, PF – DESVENLAFAXINE, desvenlafaxine 50 mg tablet: modified release, 28 tablets</td>
</tr>
<tr>
<td>9367B</td>
<td>Pristiq, PF – DESVENLAFAXINE, desvenlafaxine 100 mg tablet: modified release, 28 tablets</td>
</tr>
<tr>
<td>5541P</td>
<td>Trusopt, MK – DORZOLAMIDE, dorzolamide 2% (20 mg/mL) eye drops, 5 mL (Optometrical)</td>
</tr>
<tr>
<td>8488R</td>
<td>Trusopt, MK – DORZOLAMIDE, dorzolamide 2% (20 mg/mL) eye drops, 5 mL</td>
</tr>
<tr>
<td>8228C</td>
<td>Ikorel, SW – NICORANDIL, nicorandil 10 mg tablet, 60</td>
</tr>
<tr>
<td>8229D</td>
<td>Ikorel, SW – NICORANDIL, nicorandil 20 mg tablet, 60</td>
</tr>
<tr>
<td>8448P</td>
<td>Ursofalk, OA – URSODEOXYCHOLIC ACID, ursodeoxycholic acid 250 mg capsule, 100</td>
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**Deletions**

**Deletion – Item**

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<tr>
<td>1575X</td>
<td>FOLIC ACID, folic acid 50 mg/5 mL injection, 5 x 5 mL ampoules (Calcium Folate Ebewe)</td>
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<tr>
<td>2710P</td>
<td>MIFEPRISTONE, mifepristone 200 mg tablet, 1 (Mifepristone Linepharma)</td>
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<tr>
<td>2672P</td>
<td>MISOPROSTOL, misoprostol 200 microgram tablet, 4 (GyMiso)</td>
</tr>
<tr>
<td>2681D</td>
<td>POLYVINYL ALCOHOL, polyvinyl alcohol 3% eye drops, 15 mL (Liquifilm Forte, PVA Forte)</td>
</tr>
<tr>
<td>5525T</td>
<td>POLYVINYL ALCOHOL, polyvinyl alcohol 3% eye drops, 15 mL (Liquifilm Forte, PVA Forte) (Optometrical)</td>
</tr>
<tr>
<td>9222J</td>
<td>POLYVINYL ALCOHOL, polyvinyl alcohol 3% eye drops, 15 mL (Liquifilm Forte, PVA Forte)</td>
</tr>
<tr>
<td>2995P</td>
<td>SALCATONIN, salcatonin 50 international units/mL injection, 5 x 1 mL ampoules (Miacalcic 50)</td>
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**Deletion – Brand**

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<tr>
<td>1147J</td>
<td>APO-Captopril, TX – CAPTOPRIL, captopril 12.5 mg tablet, 90</td>
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<td>1148K</td>
<td>APO-Captopril, TX – CAPTOPRIL, captopril 25 mg tablet, 90</td>
</tr>
<tr>
<td>1149L</td>
<td>APO-Captopril, TX – CAPTOPRIL, captopril 50 mg tablet, 90</td>
</tr>
<tr>
<td>3162K</td>
<td>Diazepam-GA, GN – DIAZEPAM, diazepam 5 mg tablet, 50</td>
</tr>
<tr>
<td>5072Y</td>
<td>Diazepam-GA, GN – DIAZEPAM, diazepam 5 mg tablet, 50 (Dental)</td>
</tr>
<tr>
<td>8600P</td>
<td>Esomeprazole Actavis, GN – ESOMEPRAZOLE, esomeprazole 20 mg tablet: enteric, 30 tablets</td>
</tr>
<tr>
<td>8886Q</td>
<td>Esomeprazole Actavis, GN – ESOMEPRAZOLE, esomeprazole 20 mg tablet: enteric, 30 tablets</td>
</tr>
<tr>
<td>3401B</td>
<td>Esomeprazole Actavis, GN – ESOMEPRAZOLE, esomeprazole 40 mg tablet: enteric, 30 tablets</td>
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<tr>
<td>8601Q</td>
<td>Esomeprazole Actavis, GN – ESOMEPRAZOLE, esomeprazole 40 mg tablet: enteric, 30 tablets</td>
</tr>
<tr>
<td>2373X</td>
<td>MediHealth ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
</tr>
</tbody>
</table>
Alterations

Alteration – Item Description

From
2639X AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches (HCU cooler 10)

To
2639X AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets (HCU cooler 10)

From
2640Y AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches (HCU cooler 20)

To
2640Y AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets (HCU cooler 20)

From
2674R AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches (TYR cooler 10)

To
2674R AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets (TYR cooler 10)

From
2701E AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches (TYR cooler 20)

To
2701E AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets (TYR cooler 20)

Alteration – Brand Name

From
1891M Amoxiclav AN 500/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10

To
1891M Amoxiclav AN 500/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10

From
5008N Amoxiclav AN 500/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)

To
5008N Amoxiclav AN 500/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)

From
5006L Amoxiclav AN 875/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)

To
5006L Amoxiclav AN 875/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)

From
8254K Amoxiclav AN 875/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

To
8254K Amoxiclav AN 875/125, EA – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

From
1655D APOTEX-MORPHINE MR, TX – MORPHINE, morphine sulfate 60 mg tablet: modified release, 28 tablets

To
1655D MORPHINE MR APOTEX, TX – MORPHINE, morphine sulfate 60 mg tablet: modified release, 28 tablets

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

9033K ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira)

9034L ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira)

9101B ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (Humira)

9102C ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (Humira)

10011X DAPAGLIFLOZIN, dapagliflozin 10 mg tablet, 28 (Forxiga)

9366Y DESVENLAFAXINE, desvenlafaxine 50 mg tablet: modified release, 28 tablets (Pristiq)

9367B DESVENLAFAXINE, desvenlafaxine 100 mg tablet: modified release, 28 tablets (Pristiq)

10202Y EMPAGLIFLOZIN, empagliflozin 25 mg tablet. 30 (Jardiance)

10206E EMPAGLIFLOZIN, empagliflozin 10 mg tablet. 30 (Jardiance)

9035M ETANERCEPT, etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)

9036N ETANERCEPT, etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)

9087G ETANERCEPT, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (Enbrel)

9088H ETANERCEPT, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (Enbrel)

9457R ETANERCEPT, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (Enbrel)

9458T ETANERCEPT, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (Enbrel)

10131F EVEROLIMUS, everolimus 5 mg tablet, 30 (Afinitor)
10202Y EMPAGLIFLOZIN, empagliflozin 25 mg tablet, 30 (Jardiance) From authority-required To streamlined
10206E EMPAGLIFLOZIN, empagliflozin 10 mg tablet, 30 (Jardiance) From authority-required To streamlined

Alteration – Manufacturer Code

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Name</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1266P</td>
<td>Cyclophosphamide</td>
<td>cyclophosphamide 50 mg tablet, 50</td>
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<tr>
<td>8646C</td>
<td>Prograf</td>
<td>tacrolimus 500 microgram capsule, 100</td>
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<tr>
<td>5299X</td>
<td>Prograf XL</td>
<td>tacrolimus 500 microgram capsule: modified release, 30 capsules</td>
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<tr>
<td>8647D</td>
<td>Prograf</td>
<td>tacrolimus 1 mg capsule, 100</td>
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<tr>
<td>5300Y</td>
<td>Prograf XL</td>
<td>tacrolimus 1 mg capsule: modified release, 60 capsules</td>
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<tr>
<td>8648E</td>
<td>Prograf</td>
<td>tacrolimus 5 mg capsule, 50</td>
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<tr>
<td>5451X</td>
<td>Prograf XL</td>
<td>tacrolimus 5 mg capsule: modified release, 30 capsules</td>
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</tbody>
</table>

Advance Notices

1 May 2015

Deletion – Brand

2058H Artelac, BU – CARBOMER + TRIGLYCERIDE LIPIDS, carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses
2090B Artelac, BU – CARBOMER + TRIGLYCERIDE LIPIDS, carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses (Optometrical)

1171P Chloromycetin, PF – CHLORAMPHENICOL, chloramphenicol 1% eye ointment, 4 g
5511C Chloromycetin, PF – CHLORAMPHENICOL, chloramphenicol 1% eye ointment, 4 g (Optometrical)
1473M Fluconazole-Claris, AE – FLUCONAZOLE, fluconazole 100 mg/50 mL injection, 1 x 50 mL vial
1474N Fluconazole-Claris, AE – FLUCONAZOLE, fluconazole 200 mg/100 mL injection, 1 x 100 mL vial
2412V Fluconazole-Claris, AN – FRUSEMIDE, frusemide 40 mg tablet, 100
2414E Fluconazole-Claris, AN – FRUSEMIDE, frusemide 20 mg tablet, 100
8534E Lercanidipine AN, EA – LERCANIDIPINE, lercanidipine hydrochloride 10 mg tablet, 28
8679T Lercanidipine AN, EA – LERCANIDIPINE, lercanidipine hydrochloride 20 mg tablet, 28
1627P Tolvan, MK – MIANSERIN, mianserin hydrochloride 10 mg tablet, 50
1742Q Vagifem, NO – OESTRADIOL, oestradiol 25 microgram pessary: modified release, 15
9004X Reandron 1000, BN – TESTOSTERONE UNDECAANOATE, testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule

1 June 2015

Deletion – Brand

1172Q Chloromycetin, PF – CHLORAMPHENICOL, chloramphenicol 0.5% ear drops, 5 mL
1210Q Ciproxin 750, BN – CIPROFLOXACIN, ciprofloxacin 750 mg tablet, 14
1 July 2015

Deletion – Brand

1783W  Ceftriaxone ICP, PP – CEFTRIAXONE, ceftriaxone 500 mg injection, 1 x 500 mg vial
9058R  Ceftriaxone ICP, PP – CEFTRIAXONE, ceftriaxone 500 mg injection, 1 x 500 mg vial

1 August 2015

Deletion – Brand

2873F  Invokana, JC – CANAGLIFLOZIN, canagliflozin 100 mg tablet, 30
2987F  Invokana, JC – CANAGLIFLOZIN, canagliflozin 300 mg tablet, 30
9157Y  Sensipar, AN – CINACALCET, cinacalcet 30 mg tablet, 28
9158B  Sensipar, AN – CINACALCET, cinacalcet 60 mg tablet, 28
9159C  Sensipar, AN – CINACALCET, cinacalcet 90 mg tablet, 28

Palliative Care

Additions

Addition – Brand

2351R  Herron ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets
2353W  Herron ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

Deletions

Deletion – Brand

5356X  Diazepam-GA, GN – DIAZEPAM, diazepam 5 mg tablet, 50
5358B  Diazepam-GA, GN – DIAZEPAM, diazepam 5 mg tablet, 50
2351R  MediHealth ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets
2353W  MediHealth ClearLax, ON – MACROGOL-3350, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

10228H  ALEMTUZUMAB, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (Lemtrada)
10232M  ALEMTUZUMAB, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (Lemtrada)
10227G  APOMORPHINE, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (Apomine)
10247H  DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE, dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30 (Triumeq)
10233N  SUCROFERRIC OXYHYDROXIDE, iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90 (Velphoro)

Addition – Brand

9547L  Sildenafil AN PHT 20, EA – SILDENAFIL, sildenafil 20 mg tablet, 90

Alterations

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

5609F  APOMORPHINE, apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules (Apomine)
5610G  APOMORPHINE, apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules (Apomine)
5611H  APOMORPHINE, apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (Apomine PFS)
5756Y  INFLIXIMAB, infliximab 100 mg injection, 1 x 100 mg vial (Remicade)
5780F  LANTHANUM, LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 (Fosrenol)
5781G  LANTHANUM, LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 (Fosrenol)
5782H  LANTHANUM, LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 (Fosrenol)
9546K  SEVELAMER, sevelamer hydrochloride 800 mg tablet, 180 (Renagel)

Alteration – Manufacturer Code

9558C  Prograf – TACROLIMUS, tacrolimus 500 microgram capsule, 100
9664P  Prograf XL – TACROLIMUS, tacrolimus 500 microgram capsule: modified release, 30 capsules
9550E  Prograf – TACROLIMUS, tacrolimus 1 mg capsule, 100
9665Q  Prograf XL – TACROLIMUS, tacrolimus 1 mg capsule: modified release, 60 capsules
9561F  Prograf – TACROLIMUS, tacrolimus 5 mg capsule, 50
Advance Notices

1 August 2015

Deletion – Brand
5621W Sensipar, AN – CINACALCET, cinacalcet 30 mg tablet, 28
5622X Sensipar, AN – CINACALCET, cinacalcet 60 mg tablet, 28
5623Y Sensipar, AN – CINACALCET, cinacalcet 90 mg tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item
10243D ALEMTUZUMAB, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (Lemtrada)
10246G ALEMTUZUMAB, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (Lemtrada)
10235Q APOMORPHINE, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (Apomine)
10248J DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE, dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30 (Triumeq)
10230K SUCROFERRIC OXYHYDROXIDE, iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90 (Velphoro)

Addition – Brand
9605M Sildenafil AN PHT 20, EA – SILDENAFIL, sildenafil 20 mg tablet, 90

Alterations

Changes to Restrictions
The following items have additions, deletions or alterations to restrictions and/or notes.
9607P APOMORPHINE, apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules (Apomine)
9640J APOMORPHINE, apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules (Apomine)
9640J APOMORPHINE, apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (Apomine PFS)
6496X INFliximab, infliximab 100 mg injection, 1 x 100 mg vial (Remicade)
9635D LANTHANUM, LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 (Fosrenol)
9636E LANTHANUM, LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 (Fosrenol)
9637F LANTHANUM, LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 (Fosrenol)
9620H SEVELAMER, sevelamer hydrochloride 800 mg tablet, 180 (Renagel)

Alteration – Manufacturer Code

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<thead>
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<td>JC</td>
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<td>JC</td>
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</table>

Advance Notices

1 August 2015

Deletion – Brand
9625N Sensipar, AN – CINACALCET, cinacalcet 30 mg tablet, 28
9626P Sensipar, AN – CINACALCET, cinacalcet 60 mg tablet, 28
9627Q Sensipar, AN – CINACALCET, cinacalcet 90 mg tablet, 28

Botulinum Toxin Program

Additions

Addition – Item
10253P INCOBOTULINUMTOXINA, incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (Xeomin)
Alterations

Alteration – Restriction

6103F  BOTULINUM TOXIN TYPE A, botulinum toxin type A 100 units injection, 1 x 100 units vial (Botox)

1152P  CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX, clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial (Dysport)

6293F  CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX, clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial (Dysport)
Addresses — Department of Human Services

The Department of Human Services has responsibility for the operational aspects of the Pharmaceutical Benefits Scheme (PBS). This responsibility covers the processing of pharmaceutical benefit and safety net claims, authority applications and supply of PBS stationery used by medical practitioners, participating dental practitioners and approved pharmacists.

Procedures for ordering prescription forms are set out in the Introduction of this Schedule.

New South Wales and Australian Capital Territory

Pharmaceutical Benefits Branch
130 George Street
Parramatta NSW 2150
General and IME enquiries — Tel: 132 290

Orange Service Centre
189 Anson Street
Orange NSW 2800
General and IME enquiries — Tel: 132 290

Western Australia

Pharmaceutical Benefits Branch
Level 5, Work Distribution Centre,
(Reception on Level 4)
130 Stirling Street
Northbridge WA 6003
General and IME enquiries — Tel: 132 290

South Australia and Northern Territory

Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063
General and IME enquiries — Tel: 132 290

Tasmania

Pharmaceutical Branch
199 Collins Street
Hobart Tas 7000
General and IME enquiries — Tel: 132 290

Queensland

Pharmaceutical Services Branch
143 Turbot Street
Brisbane Qld 4000
General and IME enquiries — Tel: 132 290

National Program Management

Pharmaceutical Benefits Branch
Department of Human Services
134 Reed Street
Greenway ACT 2900
Telephone — (02) 6124 6333
Website — www.humanservices.gov.au Email — pbs@humanservices.gov.au
Authority Prescription Applications

Authority required benefits fall into two categories – Authority required and Authority required (STREAMLINED). The process in which an authority PBS prescription can be prescribed will depend on the type of Authority required benefit.

Prior approval is required for Authority required items as well as all requests for increased quantities and/or repeats for any category of PBS item.

Prior approval is not required for Authority required (STREAMLINED) items except if increased quantities and/or repeats are required (see Explanatory Notes for details).

Mail Applications:  
REPLY PAID No. 9857  
PBS Authorities Section  
Department of Human Services  
GPO Box 9857  
In your Capital City

Telephone Applications:  
Free call 1800 888 333  
Australia-wide 24 hour service PBS Authorities Section

For telephone applications please have the following information available:

Patient:  
Medicare Number  
Surname  
First name  
Full residential address (including post code)

PBS Authority Prescription Number:  
Top right hand side of the handwritten PBS Authority Form

Your Prescriber Number:  
Located below your address block on the personalised forms

Drug Information:  
PBS item  
Quantity required and number of repeats  
Daily dose  
Disease or purpose information

Requests for Drugs via the Special Access Scheme (SAS)

Requests for individual patient approval to obtain drugs that are available only through the SAS may be directed to a delegate within the Drug Safety and Evaluation Branch, Therapeutic Goods Administration, telephone (02) 6232 8111, facsimile (02) 6232 8112, or by mail to PO Box 100 Woden ACT 2606.

Department of Veterans’ Affairs

Details of the approving authority for the Department of Veterans’ Affairs are listed at the front of the Repatriation Schedule of Pharmaceutical Benefits.

Telephone Interpreter Service

A 24-hour, seven days a week telephone service is available by contacting 131 450.

The translating service (TIS) can provide immediate assistance over the telephone or arrange for an interpreter to go to a location specified in either city or country areas. The TIS service has access to 2000 professional interpreters, covering over 100 languages and dialects.
Poisons Information Centres

Phone 131 126 from anywhere in Australia — 24 hours — form information and advice on the treatment of poisoning, bites and stings

NSW
The New Children's Hospital
Hawkesbury Road
Westmead NSW 2148
Tel: (02) 9845 3111

VIC
Austin Hospital
Studley Road
Heidelberg VIC 3084
Tel: (03) 9496 4410
www.austin.org.au/poisons

WA
Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: 131 126

TAS
Tel: 131 126

NT
Tel: 131 126

ACT
Tel: 131 126

Drug Information Centres

NSW
Drug Information Pharmacist
New South Wales Medicines Information Centre
PO Box 766
Darlinghurst NSW 2010
Tel: (02) 8382 2136
OR
Drug Information Pharmacist
Hunter Drug Information Service
Newcastle Mater Misericordiae Hospital
Locked Bag 7
Hunter Regional Mail Centre NSW 2310
Tel: (02) 4921 1278
Tel: (02) 4921 1328

VIC
Drug Information Pharmacist
Austin & Repatriation Medical Centre
Studley Road
Heidelberg Vic 3084
Tel: (03) 9496 5668
OR
Drug Information Pharmacist
Drug Information Centre
Southern Health Care Network
Monash Medical Centre
246 Clayton Road
Clayton Vic 3168
Tel:(03) 9594 2361

QLD
Pharmacy Department
Royal Children's Hospital
Herston QLD 4029
Tel: 131 126

SA
Drug Information Pharmacist
Royal Adelaide Hospital
North Terrace
Adelaide SA 5000
Tel: (08) 8222 5546
OR
Drug Information Pharmacist
Flinders Medical Centre
Bedford Park SA 5042
Tel: (08) 8204 5301
OR
Drug Information Pharmacist
Queen Elizabeth Hospital
Woodville Road
Woodville SA 5011
Tel: (08) 8222 6777

THA
Drug Information Pharmacist
Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: (08) 9346 2923

NT
Drug Information Pharmacist
Royal Darwin Hospital
PO Box 41326
Casuarina NT 0811
Tel: (08) 8922 8424

ACT
Drug Information Pharmacist
Canberra Hospital
Yamba Drive
Garran ACT 2605
Tel: (02) 6244 3333
List of Contact Officers for Recalls of Therapeutic Goods

For details of consumer level recalls only — telephone 1800 020 512

These officers may be contacted —
- to obtain information about current recalls
- to report suspected problems relating to the quality, safety or efficacy of a therapeutic good

**Australian Recall Coordinator**

Mr Mick O’Connor
Bh 02 6232 8197
Mobile 0421 583 361
Fax 02 6203 1451
E-mail recalls@tga.gov.au

**Australian Capital Territory**

Mr Michael Conroy
Bh 02 6207 3974
Mobile 0418 182 375
Fax 02 6205 0997
E-mail pharmaceuticalservices@act.gov.au
Michael.i.Conroy@act.gov.au

**New South Wales**

Mr B. Battye
Bh 02 9879 3214
Mobile 0401 712 050
Fax 02 9859 5165
E-mail bruce.battye@doh.health.nsw.gov.au

Ms J. Mackson
Bh 02 9879 3214
Mobile 0411 145 562
Fax 02 9859 5165
E-mail jmack@doh.health.nsw.gov.au

**Victoria**

Ms M. Smith
Bh 03 9096 5355
Bh 1300 364 545
Mobile 0408 598 663
Fax 1300 360 830
E-mail megan.I.smith@health.vic.gov.au

Mr M. McCrone
Bh 03 9096 5066
Bh 1300 364 545
Mobile 0408 581 312
Fax 1300 360 830
E-mail matthew.mccrate@health.vic.gov.au

**Queensland**

Mr C.J. Healey
Bh 07 3328 9310
Mobile 0403 053 090
Fax 07 3328 9354
E-mail chris_healey@health.qld.gov.au

**South Australia**

Mr S. Morris
Bh 08 8204 1940
Mobile 0431 657 090
Fax 08 8226 9837
E-mail steve.morris@health.sa.gov.au

Ms E. Hender
Bh 0418 747 823
Mobile 0431 657 090
Fax 08 8226 9837
E-mail elizabeth.hender@health.sa.gov.au

**Western Australia**

Mr Neil Keen
Bh 08 9222 6883
Mobile 0419 944 801
Fax 08 9222 2463
E-mail neil.keen@health.wa.gov.au
poisons@health.wa.gov.au

**Tasmania**

Ms M. Sharpe
Bh 03 6233 3766
Ah 03 6223 3476
Fax 03 6233 3904
E-mail mary.sharpe@dhhs.tas.gov.au

Mr J. Galloway
Bh 03 6233 2064
Ah 03 6223 7074
Fax 03 6233 3904
E-mail james.galloway@dhhs.tas.gov.au

**Northern Territory**

Ms Helgi Stone
Bh 08 8922 7035
Mobile 0429 091 636
Fax 08 8922 7200
E-mail Helgi.stone@nt.gov.au

Mr T. DeZilva
Bh 08 8922 7340
Mobile 0400 251 419
Fax 08 8922 7200
E-mail tyronne.dezilva@nt.gov.au
## Index of Manufacturers' codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Manufacturer</th>
</tr>
</thead>
</table>
| **AB** | Abbott Australasia Pty Ltd  
Sir Joseph Banks Corporate Park  
32-34 Lord Street  
BOTANY NSW 2019  
Tel: 1800 801 478 |
| **AE** | AFT Pharmaceuticals Pty Ltd  
Level 1  
296 Burns Bay Road  
LANE COVE NSW 2066  
Tel: 1800 097 639 |
| **AF** | Alphapharm Pty Ltd  
Level 1  
30 The Bond, 30-34 Hickson Rd  
MILLERS POINT NSW 2000  
Tel: 1800 028 365 |
| **AG** | Allergan Australia Pty Limited  
Level 4, 810 Pacific Highway  
Gordon NSW 2072  
Tel: 1800 252 224 |
| **AL** | Alphapharm Pty Ltd  
Level 1  
30 The Bond, 30-34 Hickson Rd  
MILLERS POINT NSW 2000  
Tel: 1800 028 365 |
| **AN** | Amgen Australia Pty Limited  
Avaya House  
Level 7, 123 Epping Road  
NORTH Ryde NSW 2113  
Tel: 1800 803 638 |
| **AP** | AstraZeneca Pty Ltd  
Alma Road  
NORTH Ryde NSW 2113  
Tel: 1800 805 342 |
| **AQ** | Alcon Laboratories (Australia) Pty Ltd  
10/25 Frenchs Forest Road East  
FRENCHS FOREST NSW 2086  
Tel: 1800 025 032 |
| **AS** | Aspen Pharmacare Australia Pty Limited  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: (02) 8436 8300 |
| **AT** | Actelion Pharmaceuticals Australia Pty Ltd  
Suite 6  
13b Narabang Way  
Belrose NSW 2085  
Tel: (02) 9486 4600 |
| **AV** | sanofi-aventis Australia Pty Ltd  
Building D, Talavera Corporate Centre  
12-24 Talavera Road  
Macquarie Park NSW 2113  
Tel: +61 (0)2 8666 2000 |
| **BB** | Blackmores Limited  
20 Jubilee Avenue  
Warriewood NSW 2102  
Tel: +61 (0)2 9910 5000  
Fax: +61 (0)2 9910 5555 |
| **BD** | Biogen Idec Australia Pty Ltd  
Suite 1, Level 5  
123 Epping Road  
North Ryde NSW 2113  
Tel: +61 (0)2 8875 3900 |
| **BE** | Beiersdorf Australia Ltd  
4 Khartoum Road  
North Ryde NSW 2113  
Tel: +61 (0)2 9888 0977  
Fax: +61 (0)2 9887 3487 |
| **BG** | Sandoz Pty Ltd  
Suite 201, Level 2  
19 Harris Street  
Pyrmont NSW 2009  
Tel: 1800 726 369 |
| **BI** | Biotech Pharmaceuticals Pty Ltd  
83 Cherry Lane  
LAVERTON NORTH VIC 3026  
Tel: (03) 9278 7555 |
| **BN** | Bayer Australia Ltd  
875 Pacific Highway  
Pymble NSW 2073  
Tel: 1800 673 270 |
| **BQ** | Bristol-Myers Squibb Australia Pty Ltd  
Level 2, 4 Nexus Court  
Mulgrave VIC 3170  
Tel: 1800 067 567 |
| **BR** | B. Braun Australia Pty Ltd  
Norwest Business Park  
17 Lexington Drive  
BELLA VISTA NSW 2153  
Tel: +61 (0)2 9629 0200 |
| **BU** | Bausch & Lomb (Australia) Pty Ltd  
Ground Floor  
16 Giffnock Avenue  
MACQUARIE PARK NSW 2113  
Tel: (02) 9887 1444 |
| **BV** | B.S.N.  
315 Ferntree Gully Road  
Mount Waverley VIC 3149  
Tel: +61 (0)3 8540 6777 |
| **BX** | Baxter Healthcare Pty Limited  
1 Baxter Drive  
OLD TOONGABBIE NSW 2146  
Tel: 1300 789 646 |
| **BY** | Boehringer Ingelheim Pty Ltd  
78 Waterloo Road  
NORTH Ryde NSW 2113  
Tel: (02) 8875 8600 |
| **BZ** | Boucher & Muir Pty Ltd  
Level 1, 134 Willoughby Road  
Crows Nest NSW 2065  
Tel: 1800 627 680 |
| **CC** | ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd  
606 Hawthorn Road  
East Brighton VIC 3187  
Tel: 1800 335 276 |
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| IV   | iNova Pharmaceuticals (Australia) Pty Limited  
Po Box 5033  
WEST CHATSWOOD NSW 2067  
Tel: +61 (0)2 8918 6322  
Fax: +61 (0)2 8918 6415 |
| IX   | Clinect Pty Ltd  
Level 3, 484 St Kilda Road  
Melbourne VIC 3004  
Tel: (03) 9918 5555 |
| JC   | Janssen-Cilag Pty Ltd  
1-5 Khartoum Road  
North Ryde NSW 2113  
Tel: +61 (0)2 8875 3333  
Fax: +61 (0)2 8875 3300 |
| JN   | JNS Biomedical Pty Ltd  
99 Finlayson Street  
Rosanna VIC 3084  
Tel: +61 (0)3 9913 4660 |
| JT   | Johnson & Johnson Medical Pty Ltd  
1-5 Khartoum Road  
North Ryde NSW 2113  
Tel: +61 (0)2 9815 4276 |
| KE   | Kendall Australasia Pty Ltd  
22 Giffnock Avenue  
North Ryde NSW 2113  
Tel: 1800 252 467 |
| KL   | KCI Medical Australia Pty Ltd  
Level 7, 15 Orion Road  
Lane Cove West NSW 2066  
Tel: 1800 815 529  
Fax: +61 (0)2 9422 4344 |
| KP   | Eli Lilly Australia Pty Ltd  
112 Wharf Road  
West Ryde NSW 2114  
Tel: (02) 9325 4444 |
| KY   | Key Pharmaceuticals Pty Ltd  
12 Lyon Park Road  
MACQUARIE PARK NSW 2113  
Tel: (02) 8113 6200 |
| LL   | Astellas Pharma Australia Pty Ltd  
Level 4, 6 Eden Park Drive  
Macquarie Park NSW 2113  
Tel: 1800 751 755 |
| LM   | Link Medical Products Pty Ltd  
Unit 1  
5 Apollo Street  
WARRIEWOOD NSW 2102  
Tel: +61 (0)2 8401 9777 |
| LN   | Aspen Pharmacare Australia Pty Limited  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: (02) 8436 8300 |
| LO   | Leo Pharma Pty Ltd  
Level 3, Tower 1  
25 Montpelier Road  
 Bowen Hills QLD 4006  
Tel: (07) 32501200 |
| LS   | Astellas Pharma Australia Pty Ltd  
Level 4, 6 Eden Park Drive  
Macquarie Park NSW 2113  
Tel: 1800 751 755 |
| LU   | Lundbeck Australia Pty Ltd  
Ground Floor  
1 Innovation Road  
NORTH RYDE NSW 2113  
Tel: (02) 88691000 |
| LY   | Eli Lilly Australia Pty Ltd  
112 Wharf Road  
West Ryde NSW 2114  
Tel: (02) 9325 4444 |
| MD   | Roche Products Pty Ltd  
4-10 Inman Road  
DEE WHY NSW 2099  
Tel: +61 (0)2 9454 9000  
Fax: +61 (0)2 9971 7401 |
| MF   | Mundipharma Pty Limited  
50 Bridge Street  
SYDNEY NSW 2000  
Tel: 02 9231 7200 |
| MH   | Molinlycke Health Care Pty Ltd  
Building 1, Ground Floor 14 Aquatic Drive  
Frenchs Forest NSW 2086  
Tel: +61 (0)2 9453 1144  
Fax: +61 (0)2 9453 1155 |
| MK   | Merck Sharp & Dohme (Australia) Pty Ltd  
Level 1, Building A  
26 Talavera Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 8988 8000 |
| MM   | 3M Pharmaceuticals Australia Pty Ltd  
9-15 Chilvers Road  
Thornleigh NSW 2120  
Tel: (02) 9875 6333 |
| MQ   | Alphapharm Pty Ltd  
Level 1  
30 The Bond, 30-34 Hickson Rd  
MILLERS POINT NSW 2000  
Tel: 1800 028 365 |
| MS   | Abbott Australasia Pty Ltd  
Sir Joseph Banks Corporate Park  
32-34 Lord Street  
BOTANY NSW 2019  
Tel: 1800 801 478 |
| MT   | Mentholatum Australasia Pty Ltd  
12-16 Janine Street  
Scoresby VIC 3179  
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# Index of Manufacturers' codes

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Suite 129  
135 Cardigan Street  
Carlton VIC 3053  
Tel: 1300 515 883  
Fax: +61 (0)3 9658 7449 |
| XI   | Alexion Pharmaceuticals Australasia Pty Ltd  
Suite 226-227  
117 Old Pittwater Road  
Brookvale NSW 2100  
Tel: +61 (0)2 9091 0500  
Fax: +61 (0)2 9091 0511 |
| XM   | The Medicines Company (Australia) Pty Limited  
Suite 1  
Level 8, North Tower, 1-5 Railway Street  
CHATSWOOD NSW 2067  
Tel: 1800 755 459 |
| YN   | Mayne Pharma International Pty Ltd  
Level 14  
474 Flinders Street  
MELBOURNE VIC 3000  
Tel: 1300 081 849 |
| YT   | Mayne Products Pty Ltd  
Level 14  
474 Flinders Street  
MELBOURNE VIC 3000  
Tel: 1300 081 849 |
| ZF   | Sun Pharmaceutical Industries (Australia) Pty Ltd  
1053 Burwood Highway  
FERNTREE GULLY VIC 3156  
Tel: (03) 95686102 |
| ZI   | Shire Australia Pty Limited  
Avaya House  
Level 6, 123 Epping Road  
North Ryde NSW 2113  
Tel: 1800 012 612 |
| ZP   | Medis Pharma Pty Ltd  
L3, 5 Essex St, The Rocks  
Sydney NSW 2000  
Tel: +61 (0)2 8220 4650  
Fax: +61 (0)2 9251 1099 |
| ZX   | Zenex Pharmaceuticals Pty Ltd  
21 Mutimer Street  
Preston VIC 3072  
Tel: +61 (0)4 1378 2370 |
Section 1 — Explanatory Notes

Introduction

These Explanatory Notes are provided to help PBS prescribers and pharmacists work within the Australian Government’s Pharmaceutical Benefits Scheme (PBS).

The PBS is a system of subsidising the cost of most prescription medicines. The subsidies are available to all Australian residents and eligible foreign visitors, i.e., people from countries which have Reciprocal Health Care Agreements with Australia. These countries are the United Kingdom, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium and Slovenia.

The aim of the PBS, which has been in operation since 1948, is to provide reliable and affordable access to a wide range of necessary medicines. The Schedule of Pharmaceutical Benefits referred to throughout as the ‘Schedule’ – lists all the medicinal products available under the PBS, and explains the uses for which they can be subsidised.

The Schedule is produced monthly by the Australian Department of Health (effective on the first day of each month).

It is vital therefore that PBS prescribers and pharmacists remain up to date with information on which medicines are included in or excluded from the Schedule, which PBS prescribers may prescribe certain medicines, whether restrictions apply to the medicines, and how much patients should pay.

Queries relating to the PBS can be made to the Pharmaceutical Benefits Branch of the Department of Human Services (telephone 132 290 open 24 hours a day, 7 days a week). Queries relating to the Repatriation Pharmaceutical Benefits Scheme (RPBS) can be made to the State offices of the Department of Veterans’ Affairs (DVA) (telephone 1800 552 580).

1. The Schedule — Where to Find What

The Schedule of Pharmaceutical Benefits is divided into sections. At the start of the Schedule, immediately after the table of contents, is a summary of any changes to listed items. This is followed by a list of important information sources, contacts and addresses, then an index of manufacturers’ codes.

The last pages of the Schedule provide a generic/proprietary index of PBS and RPBS ready-prepared items.

Section 1

Section 1 is what you are reading, the Explanatory Notes. It outlines the correct way to prescribe and supply pharmaceutical benefits; patient charges; who qualifies for concessions; how the Safety Net system works; and, for pharmacists, how to claim reimbursement for PBS items.

Please note that except where indicated, the term ‘prescriber’ is used in this section to cover doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.

And except where stated otherwise, the term ‘pharmacist’ means a pharmacist approved to supply medicines under the PBS.

Section 2

This section lists ready-prepared items, and includes the form, manner of administration, brand and brand equivalents which may be prescribed, and the maximum quantity and number of repeats for each item.

Prescriber bag supplies are also listed at the beginning of this section.

Medicines that have restrictions on how they can be prescribed are printed in bold italics. Items appearing in more than one therapeutic group are cross-referenced.

The second page of Section 2 explains symbols used throughout the Schedule.

The use of ‘NOTE’ in this section is used to clarify how some pharmaceutical benefits should be prescribed.

The use of ‘CAUTION’ is to warn of known adverse reactions from, or precautions to be taken with, a particular pharmaceutical benefit. (The absence of a cautionary note does not imply reactions may not happen.)

Separate lists at the end of Section 2 relate to items that can be prescribed by dentists and optometrists who work within the PBS. These are followed by a list of items that are made available under special arrangements for doctors to prescribe.

Section 3

This section lists container prices, fees related to dispensing, standard packs and prices for ready-prepared preparations.
Section 4

This section deals with extemporaneous preparations. It lists the ingredients which can be used, a table of maximum quantities and number of repeats, container prices, and a list of standard formula preparations and prices (based on formularies in common use and referred to in the Schedule as the Standard Formulae List).

Restrictions applying to the use of a pharmaceutical benefit are indicated against the item.

Repatriation Schedule of Pharmaceutical Benefits

After Section 4, the Schedule provides information about pharmaceutical benefits under the RPBS. These may only be prescribed to DVA beneficiaries holding one of the repatriation health cards (see details under ‘4. Patient Charges’).

2. Prescribing Medicines – Information for PBS Prescribers

PBS prescribers

Pharmaceutical benefits can only be prescribed by doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication from a hospital. The States of Victoria, Queensland, South Australia, Western Australia and Tasmania, and the Northern Territory have agreed to implement these arrangements.

PBS Prescription forms

Standard PBS prescription forms are available from the Department of Human Services for prescribing pharmaceutical benefits.

For doctors:
- **Personalised forms** — are printed with the doctor's name, qualifications, practice address/es, telephone number and prescriber number (which relates to pharmaceutical benefits). They are only provided to doctors who have a Medicare provider number.
- **Non-personalised (blank) forms** — are distributed as an emergency supply (usually when a doctor has temporarily run out of personalised forms).
- **Locum forms** — have the doctor’s name, prescriber number and telephone number (if available) and a space to record the practice where the doctor is working.
- **PBS/RPBS Authority Prescription Forms** — can be in personalised, non-personalised or locum format.
- **Computer PBS prescription forms** — are either continuous or single sheet. On the reverse side they list the name, address and telephone number of the practice, and in the case of a sole doctor practice, the doctor’s name.

For dentists:
- **Personalised forms** — have the dentist’s name, qualifications, practice address/es, telephone number and prescriber number.
- **Non-personalised (blank) forms** — are distributed for emergency supply only.

For optometrists:
- **Personalised forms** — have the optometrist's name, qualifications, practice address/es, telephone number and prescriber number. These forms can be also used to prescribe authority-required PBS/RPBS items.

For midwives:
- **Personalised forms** — have the midwife’s name, qualifications, practice address/es, telephone number and prescriber number.
- **Non-personalised (blank) forms** — are distributed for emergency supply only.

For nurse practitioners:
- **Personalised forms** — have the nurse practitioner’s name, qualifications, practice address/es, telephone number and prescriber number.
- **Non-personalised (blank) forms** — are distributed for emergency supply only.

PBS prescription forms for PBS prescribers are supplied free of charge.

The inclusion of the prescriber number on a PBS prescription enables the pharmacist to be sure the prescription is from a legitimate prescriber and satisfies State/Territory legislation. A PBS prescription written by a dentist, an optometrist, a midwife or a nurse practitioner must include the person’s approval number as a PBS prescriber.
PBS prescriptions should be provided to the patient in duplicate, as both parts make up a valid PBS prescription. The patient should be reminded to present both the original and the duplicate copy to the pharmacist.

**PBS stationery order forms**

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time. Prescribers can gain access to order forms for standard and authority prescription forms as well as computer prescription forms by downloading the required order form from the Department of Human Services website at www.humanservices.gov.au.

The completed order form should be posted to:

Prescription Pad Order Clerk  
Pharmaceutical Branch  
Department of Human Services  
GPO Box 9826  
Sydney NSW 2001  
Telephone (02) 9895 3295

**Preparing general PBS prescriptions**

*Do’s and Don’t’s*

A PBS prescription is only valid when it is written by a doctor, a dentist, an optometrist, a midwife or a nurse practitioner. The PBS prescription must be for the treatment of the person named on the PBS prescription. A PBS prescription may only be written for the treatment of one person.

A prescriber cannot write more than one PBS prescription for the same pharmaceutical benefit for the same person on the same day.

Up to three pharmaceutical benefit items may be included on a single PBS prescription form except for Authority required, Authority required (STREAMLINED) items and optometrist items. These items must be written on individual forms. Pharmaceutical benefits and non-pharmaceutical benefits should not be listed together on the one PBS prescription form.

If an item has a particular manner of administration it may not, as a pharmaceutical benefit, be administered in any other way, e.g., an ophthalmic preparation may not be prescribed for topical use.

If an item is restricted, and the use for the patient is different from the use specified in the restriction, it cannot be prescribed as a pharmaceutical benefit. The prescriber should write the prescription as a non-PBS private prescription. If a standard PBS prescription form is used for this purpose the ‘PBS/RPBS’ text must be clearly struck out. It should also be endorsed ‘non-PBS’.

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted in the poisons legislation of the particular State or Territory. Legislative requirements in some States/Territories are such that prescribers may be required to prescribe a drug of addiction on a separate PBS prescription. Prescribers must ensure that prescriptions written under the PBS fall within the limits of the prescribing approval granted to the person under State or Territory requirements. It is the prescriber’s responsibility to ensure that PBS prescriptions comply with all aspects of his/her prescriber approval. Inclusion of a PBS medicine for prescribing does NOT confer approval for a particular prescriber to prescribe that medicine if it is not authorised to be prescribed in a particular State or Territory.

A PBS prescriber cannot prescribe a narcotic drug for him/herself.

Prescribers are issued with individual PBS prescription pads by the Department of Human Services for their own use — these pads should not be used by other prescribers.

Doctors should, and dentists and optometrists, midwives and nurse practitioners are required to, include their prescriber number on non-personalised PBS prescriptions.

The following admixtures are not pharmaceutical benefits:

- the admixture of two or more ready-prepared items listed in the Schedule; or
- the admixture of a ready-prepared item and one or more extemporaneous drugs listed in Section 4 of the Schedule; or
- the admixture of a non-pharmaceutical benefit item with a pharmaceutical benefit item.

**Writing the PBS prescription**

The following rules apply for writing PBS prescriptions:

- they must be written in indelible form (i.e., ink or ball-point pen) in the prescriber’s own handwriting (exceptions must be approved by Chief Executive Medicare) either on the standard PBS prescription, or on paper approximately 18 cm x 12 cm, or they can be generated by computer on a form approved by the Department of Human Services. For patient safety reasons, both the original and the duplicate must be legible;
- they must record the prescriber’s name and address (and, in the case of dentists, optometrists, midwives and nurse practitioners, the prescriber number), the patient’s name, address and entitlement status, and whether the prescription is under the PBS or RPBS;
they should completely identify the pharmaceutical benefit by detailing the item, dose, form, strength, quantity and instructions for use; they should indicate where brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all prescriptions being indicated as Brand Substitution Not Permitted; and they must be signed by the prescriber and dated. Forward or back dating is not permitted.

Restrictions
Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits - have no restrictions on their therapeutic uses;

Restricted benefits - can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits - Authority required benefits fall into two categories:

• Authority required benefits are restricted benefits that require prior approval from the Department of Human Services or the DVA (noted as Authority required);
• Authority required (STREAMLINED) benefits are restricted benefits that do not require prior approval from the Department of Human Services or the DVA but require the recording of a streamlined authority code (noted as Authority required(STREAMLINED)).

Authority PBS prescriptions
Authority required benefits fall into two categories - Authority required and Authority required (STREAMLINED).

All PBS prescribers (with the exception of dentists) can write authority PBS prescriptions. Authority PBS prescriptions cannot have retrospective approval.

Authority required PBS Prescriptions
Approval of authority PBS prescriptions by Chief Executive may be sought by:

• posting an Authority Prescription Form to the Department of Human Services - after approval, the Department of Human Services will forward both copies of the prescription to the patient or the prescriber (if it is to be sent direct to the patient, the prescriber should mark the box next to the patient’s details);
• calling the Department of Human Services Telephone Authority Applications Freecall service (1800 888 333); or

Approval of authority prescriptions by the DVA may be obtained either by posting an Authority Prescription Form to the DVA, or by using the DVA Authority Freecall service (1800 552 580).

An authority PBS/RPBS prescription is not valid until it has been approved by the Department of Human Services or the DVA. Without this approval, a pharmacist must not supply the item as a PBS/RPBS benefit.

Each Authority required PBS/RPBS item must be written on an Authority PBS/RPBS prescription form, one item per form. Authority PBS prescription forms provide for the following:

• the patient/pharmacist copy, which records prescriber, patient, and pharmaceutical benefit item details. Where required a repeat authorisation, which is used for repeat supply, is attached to the pharmacist/patient copy until the last supply is made. The patient/pharmacist copy is then retained by the pharmacist;
• the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;
• the prescriber’s copy (for computer generated scripts, this is the tear off portion at the base of the script) or Prescriber/the Department of Human Services/DVA copy (for handwritten scripts this is the long white copy), is kept by the Department of Human Services or the DVA for record purposes when approval is sought in writing. When approval is by telephone or by the authorities website, the prescriber must keep this copy for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient’s age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

Authority required (STREAMLINED) PBS Prescriptions
Prior approval is not required from the Department of Human Services or DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

This code is listed with the corresponding restriction for each Authority required (STREAMLINED) item and the prescriber must write the code on the authority PBS/RPBS prescription form. An authority prescription for an Authority required (STREAMLINED) item is not valid unless the code is included on the prescription form. Without the streamlined authority code, a pharmacist must not supply the item as a PBS benefit.

There are no Authority Required (STREAMLINED) items in the Repatriation Schedule of Pharmaceutical Benefits.
Authority required (STREAMLINED) PBS prescriptions must be written on an Authority PBS/RPBS Prescription Form, this includes:

- the pharmacist/patient copy, which records prescriber, patient, and pharmaceutical benefit item details. The prescription is given directly to the patient to be dispensed at their pharmacy;
- the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;
- the prescriber’s copy is kept by the prescriber for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient’s age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

Writing authority PBS prescriptions

The following rules apply:

- only one item may be prescribed per PBS prescription;
- PBS prescriptions must be completed by prescribers in writing, unless otherwise approved by the Department of Human Services;
- prescribers should include their name, address, telephone number and prescriber number (not provider number);
- prescribers must include the patient’s name, address and entitlement status (i.e. whether they are a ‘concessional’ or ‘general patient’);
- prescribers must indicate when brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all PBS prescriptions being indicated as Brand Substitution Not Permitted;
- in certain circumstances, the prescriber must provide additional information to the Department of Human Services with the authority application; and
- the PBS prescription must be signed by the prescriber and dated.

Posted applications which lack necessary information, and therefore cannot be approved, will be returned for correction. If the matter can be clarified via telephone, an Authority to Prescribe Form may be prepared by the Department of Human Services or the DVA and sent to the prescriber.

In the case of authority PBS prescriptions approved by telephone, the approval number must be included on the PBS prescription to enable the pharmacist to supply the medication. A prescriber who is granted approval but decides not to continue with the therapy should advise the Department of Human Services.

In the case of Authority required (STREAMLINED) prescriptions, the streamlined authority code must be written on the PBS/RPBS prescription form. This enables the pharmacist to supply the medication as a PBS benefit.

Maximum quantities and repeats

The maximum quantity and number of repeats allowed for PBS items are recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). In the case of RPBS items, the recommendations are made by the Repatriation Pharmaceutical Reference Committee (RPRC).

There are no repeats included in PBS listings for items for prescribing by dentists.

PBS prescriptions and repeats can be for any quantity up to the maximum. It is not necessary to prescribe the maximum quantity if a lesser quantity is sufficient for the patient’s needs. Please clearly indicate the number of tablets, capsules, etc. required and the number of repeats needed, and do not use abbreviations such as ‘Max. Qty’, ‘M.Q.’, or ‘M.R.’.

If a prescriber feels the maximum quantity or number of repeats should be increased for a particular patient, he or she must complete an Authority PBS Prescription Form (see procedures above under ‘Authority PBS Prescriptions’). The provision of increased quantities and repeats on authority PBS prescriptions is intended to provide approximately one month’s therapy which may be repeated (if clinically appropriate) to provide 6 months’ therapy in total. This situation usually arises where higher than normal dosages are required.

Approval for increased quantities and repeats of Authority required, Authority required (STREAMLINED) and Restricted benefit PBS items will be granted only where the reason for the PBS prescription is consistent with the indications published in the Schedule.

Approval for increased quantities and repeats extends only to the provision of a pharmaceutical benefit for the patient and does not imply approval of any aspects of the patient’s care, which are the responsibility of the treating prescriber.

Regulation 24

Under this regulation, original and repeat supplies of pharmaceutical benefits can be supplied at the one time if a medical practitioner, a midwife or a nurse practitioner is first satisfied that certain conditions apply, then endorses the PBS prescription ‘Regulation 24’. RPBS prescriptions may be endorsed ‘hardship conditions apply’.

The medical practitioner, midwife or nurse practitioner must first be satisfied all the following conditions apply:

- the maximum PBS quantity is insufficient for the patient’s treatment; AND
- the patient has a chronic illness or lives in a remote area where access to PBS supplies is limited; AND
- the patient would suffer great hardship trying to get the pharmaceutical benefit on separate occasions.

Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.
**Urgent cases**

In urgent cases and where State/Territory law allows, a prescriber may telephone a pharmacist and ask that a PBS prescription be supplied. He/she must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

This also applies to 'Authority required' authority PBS prescriptions provided prior approval has been given by the Department of Human Services or DVA. The follow-up written PBS prescription must include the approval number provided over the phone by the Department of Human Services or DVA.

**Drugs of addiction**

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from, the appropriate health authority.

When a PBS/RPBS authority application is for a drug of addiction (other than dexamphetamine sulfate), the following guidelines apply:

- the maximum quantity authorised is generally for one month’s therapy (e.g., one week’s therapy with three repeats);
- where supply for a longer period is warranted, quantities are usually for up to three months’ therapy;
- telephone approvals are limited to one month’s therapy.

Prescribers should also state the interval of repeat where repeats are called for, and ensure State/Territory health authorities are notified about ongoing treatment.

**Prescriber bag supplies**

Certain pharmaceutical benefits are provided without charge to prescribers who in turn can supply them free to patients for immediate administration or emergency use.

A drug or a pharmaceutical benefit (as a particular form of a drug), may be available for general prescribing and prescriber bag supply, or via prescriber bag provisions only (ie. not for prescribing as a general pharmaceutical benefit). Prescriber bag items are listed according to the PBS prescribers who may obtain and supply them, and may be listed for one or more PBS prescriber types.

To obtain supplies, a prescriber bag supply order form must be completed in triplicate, signed, and the original and duplicate given to a pharmacist. Each form is valid for the month indicated on the form.

Prescribers may order up to the maximum quantity of an item provided they do not already have the maximum quantity on hand. No more than the maximum quantity can be obtained in a calendar month. Prescribers may order a particular brand of a pharmaceutical benefit. A change to specify another listed brand must be initialled by the prescriber.

A receipt must be signed by the prescriber, or by an authorised representative, when supplies are received.

**Improving the capacity of the PBS to meet particular Aboriginal and Torres Strait Islander health needs**

The PBS includes listings to support the treatment of conditions common in Aboriginal and Torres Strait Islander health settings. These listings are specifically for your patients who identify as Aboriginal and/or Torres Strait Islander persons. Some listings will be medicines recently added to the PBS; others may contain specific restrictions for existing PBS items.

More information is available on the Factsheet: Listings on the PBS for Aboriginal and Torres Strait Islander people

A significant proportion of the higher levels of illness experienced by Aboriginal and Torres Strait Islanders may be addressed through better access to appropriate medicines. The PBS aims to provide greater choice in therapeutic options and to address:

- the greater burden of disease experienced by Aboriginal and Torres Strait Islander peoples; and
- morbidity almost exclusively seen in this population.

**How to prescribe these items?**

These items are available as "Authority PBS prescriptions". You should obtain approval from the Department of Human Services before prescribing these items for patients who identify as Aboriginal and/or Torres Strait Islander persons through the Authority Freecall service [1800 888 333], on line or by mail.

All PBS prescribers except dentists can write Authority PBS prescriptions and your patients will be required to pay their normal PBS co-payment.

Special arrangements apply in remote area Aboriginal Health Services for supplying these PBS items.

**Aboriginal and Torres Strait Islander identification**

Establishing a client's background may have clinical significance and should be part of routine medical history taking. In the case of Aboriginal and Torres Strait Islander people, this is also relevant to establish eligibility for services such as health checks, specific immunisation programs, and the some PBS items.

Improving the level of identification of Aboriginal and Torres Strait Islander people will also assist in developing initiatives to meet particular needs.
For the purposes of these PBS items a person is Aboriginal and/or Torres Strait Islander if the person identifies himself or herself as being an Aboriginal and/or Torres Strait Islander. Clients should be asked to self-identify either verbally or by completing a form.

- Some people may give this information without being asked.
- It is important not to assume that a person is or is not Aboriginal or Torres Strait Islander.

**Asking about Aboriginal and/or Torres Strait Islander identification**

Practitioners should ensure that each person attending their practice has the opportunity to identify if they are Aboriginal or Torres Strait Islander. An environment which maintains confidentiality and provides an explanation for this question if requested will assist this process.

- The inquiry may be made verbally and recorded by the general practitioner as part of routine medical history taking at first consultation, or by a receptionist or other staff member. An appropriate question to ask is: "Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
- Alternatively, the question may be included on a client self-history or practice record form, using a standard question such as: "Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
  - Yes - Aboriginal
  - Yes - Torres Strait Islander
  - Yes - Aboriginal and Torres Strait Islander
  - No

**Aboriginal and Torres Strait Islander health**

Major causes of excess mortality in Aboriginal and Torres Strait Islander peoples are:

- circulatory conditions (including ischaemic heart disease, hypertension, cerebrovascular disease and rheumatic heart disease);
- external causes (including accident and injury);
- endocrine causes (mainly type two diabetes and its complications); and
- respiratory conditions.

Causes of morbidity vary but include the risk factors and precursors of all of these. They also include infections of the respiratory system, the ears (in particular, chronic suppurative otitis media), the eyes (trachoma in some settings), the skin and the gastrointestinal system. End-stage renal disease is a major cause of hospitalisations, and much early renal disease remains undetected. In some settings, sexually transmissible infections are common.

Living environments affect health and may be compromised by overcrowding, limited access to clean water and sanitation, and poverty. Social and family life may be negatively influenced by an excessive burden of care for family members, by substance use and sometimes by family violence.

**Communication and cultural issues**

Aboriginal cultures are numerous and diverse in language, customs, non-verbal and verbal communication, geographical locations and experiences. Torres Strait Islanders are a separate people with a distinctly different culture and identity. Aboriginal and Torres Strait Islander people often perceive health differently from other Australians.

*For Aboriginal and Torres Strait Islander peoples’ health does not just entail the freedom of the individual from sickness but requires support for healthy and interdependent relationships between families, communities, land, sea and spirit. The focus must be on spiritual, cultural, emotional and social well-being as well as physical health*


To provide effective primary health care to Aboriginal and Torres Strait Islander clients, you need to be aware of the issues surrounding this diversity, and which may have an impact on the delivery of services.

- Aboriginal and Torres Strait Islander people may be reluctant to use mainstream medical services. This may be because of a lack of understanding of the mainstream health system and previous negative experiences within the mainstream health care system.
- Access to adequate health care may be hindered by family obligations (often extended family), lack of transport or money, or geographical isolation.
- English may be the person’s second, third or even fourth language. Therefore it may be appropriate to consider the use of an interpreter.
- Aboriginal and Torres Strait Islander people may be reluctant to consult a health care provider of the opposite sex, particularly with regard to women’s and men’s health issues.

The differences between the cultural and language backgrounds of health service providers and patients, whether urban, rural or remote, may range from minor to extreme.

You should:

- Make efforts to ensure waiting rooms are welcoming to Aboriginal and Torres Strait Islander people, including displaying relevant posters and pamphlets;
- Provide a relaxed setting for the consultation (e.g. sit next to your patient rather than across a desk);
- Allow time at the first consultation to build rapport and trust;
• Ensure the person understands clearly what the service entails and the details of any procedures involved, and possible follow-up or referral requirements;
• Obtain health promotion information appropriate for Aboriginal and Torres Strait Islander patients;
• Allow the patient to have family members present if desired. When inviting family or community members to accompany a patient, ensure the patient fully consents to their attendance and that the community/family members are fully aware of the need for confidentiality;
• Provide gender appropriate staff where possible, for both male and female patients, especially in regard to pap smears, mammograms, sexual health checks, pregnancy checks, antenatal care and postnatal care;
• Encourage all staff in the practice to attend Aboriginal and Torres Strait Islander Cultural Awareness programs, which are widely available;
• Ensure practice staff have awareness of appropriate referral and/or support organisations for Aboriginal and Torres Strait Islander patients; and
• Develop partnerships with local Aboriginal and Torres Strait Islander community organisations.

For more information, pbs-indigenous@health.gov.au

3. Supplying Medicines — What Pharmacists Need to Know

Eligible suppliers
Pharmaceutical benefits are mainly supplied by approved pharmacists – pharmacists who comply with certain conditions. These pharmacists are approved to dispense pharmaceutical benefits from a particular pharmacy.

Other suppliers include approved doctors (usually practising in isolated areas), Friendly Society pharmacies, and approved hospitals. All suppliers are issued with approval numbers by the Department of Human Services. They should follow the procedures in these Explanatory Notes.

An approved pharmacist may only supply pharmaceutical benefits at or from premises for which they have been approved.

Unapproved pharmacists cannot supply pharmaceutical benefits.

Conditions of Approval for approved pharmacists
The National Health Act 1953 (the Act) allows for payment of a claim for the supply of a pharmaceutical benefit where the supply has been made at or from premises for which the pharmacist is approved under the Act (approved premises).

The Act also provides that payment to an approved pharmacist for the supply of a pharmaceutical benefit cannot be made if it was supplied at or from unapproved premises, or otherwise than in accordance with a condition of approval.

As part of their approval under section 90 of the Act, all approved pharmacists are subject to certain conditions. These include that the approved pharmacist will:

• not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution;
• clearly advertise that any offer for free or cut-price medicines does not include pharmaceutical benefits which have a Commonwealth contribution; and
• not pay rebates or refunds of patient contributions.

The Act also allows the Minister to determine any other conditions with which approved pharmacists must comply. These additional conditions are set out in the National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007 (the Conditions of Approval). The Conditions of Approval require that an approved pharmacist must, amongst other requirements:

• comply with all legal requirements for the practice of pharmacy;
• comply with the Pharmaceutical Society of Australia’s Code of Ethics and Professional Practice Standards in their dealings with each individual patient; and
• maintain the currency of his or her pharmaceutical knowledge in accordance with the Pharmaceutical Society of Australia’s Competency Standards for Pharmacists in Australia.

From 1 December 2014, a new condition of approval is being introduced which sets out the circumstances which must be met before a claim for payment from the commonwealth for the supply of a Pharmaceutical Benefit can be made.

This new condition requires that an approved pharmacist must not make a claim for payment for the supply of a pharmaceutical benefit unless it was supplied at or from approved premises for the pharmacist.

To assist approved pharmacists in understanding the intention of the proposed new condition of approval the Department has prepared a series of Frequently Asked Questions.

Frequently Asked Questions – (Word 30 KB)
Frequently Asked Questions - (PDF 109 KB)

Approved pharmacists should be aware that a breach of a condition of approval may lead the following compliance measures:

• recovery of monies;
• reprimand, suspension or revocation of approval (following referral to the Pharmaceutical Services Committee of Inquiry); and/or
• prosecution for criminal offence under the Act or Criminal Code.
Should you have concerns about a potential breach of the Conditions of Approval for approved pharmacists, or any other compliance matter, you can report your concerns to The Australian Government Services Fraud Tip-off Line by calling 131 524 or filling out the Reporting suspected fraud (1980) form.

The Department of Human Services investigates all tip-offs related to payments that may have been made incorrectly. However, the Department is not able to provide complainants with updates due to legislated privacy and secrecy provisions. For more information on how to report your concerns, please visit the Department of Human Services website.

**Other requirements for approved pharmacists**

A pharmacist approved to supply medicines under the PBS:

- will publicly display a notice setting out the pharmacy’s normal trading hours;
- is obliged to supply pharmaceutical benefits at the pharmacy at any hour if a PBS prescription is marked ‘urgent’ and initialled by the prescriber;
- will keep adequate stocks for the supply of pharmaceutical benefits;
- may be called on by the Department of Human Services to provide details of stocks of pharmaceutical benefits or preparations for pharmaceutical benefits; and
- must keep the duplicates of all old format PBS prescriptions, and the patient/pharmacist copies of all new format PBS prescriptions, with a Commonwealth contribution for at least one year from the date of supply. This includes PBS prescriptions ordering repeats when it is the final supply, and order forms for prescriber bag supplies. Please note that some State/Territory laws require these copies to be kept for longer periods.

**Before supplying pharmaceutical benefits**

Several steps must be taken before a pharmaceutical benefit is supplied.

Firstly, a pharmacist must endorse the PBS prescription and duplicate with his/her name and approved supplier number.

Secondly, a PBS prescription identifying number must be given to the PBS prescription item on both the PBS prescription and duplicate. Any recognised series of numbers may be used.

If more than one item is on a PBS prescription, a separate identifying number should be allocated to each item.

In the case of a repeat authorisation, the same PBS prescription identifying number(s) must be carried through for each item. A pharmacist must also allocate his/her own identifying number on the repeat authorisation. It must be written alongside the date and place of supply.

**Supplying pharmaceutical benefits**

**Do’s and Don’ts**

Except in urgent cases (see details under ‘2. Prescribing Medicines ... Urgent cases’), pharmacists are authorised to supply pharmaceutical benefits only after they receive:

- the pharmacist/patient and the Department of Human Services or DVA copies of a valid PBS prescription which is not more than 12 months old; or
- the pharmacist/patient and the Department of Human Services or DVA copies of an approved authority PBS prescription or an authority to prescribe which is not more than 12 months old; or
- a repeat authorisation attached to a patient/pharmacist PBS prescription not more than 12 months after the date of the original PBS prescription.

A pharmacist must not supply an Authority required (STREAMLINED) item unless the prescriber has written the four digit streamlined authority code on an authority PBS/RPBS prescription.

A pharmaceutical benefit cannot be supplied more times than specified in the PBS prescription.

A pharmacist cannot add to, delete from, or alter a PBS prescription in any other way. However, there may be circumstances where after contacting a prescriber, the pharmacist can clarify the prescriber’s intentions and endorse the PBS prescription accordingly.

Once a pharmaceutical benefit has been supplied to a patient, it may not be supplied to that patient again:

- on the same day or within the next 20 days, if it is a benefit (other than an eye preparation) that has five or more repeats allowed in the Schedule; or
- on the same day or within the next four days (e.g., if a pharmaceutical benefit is supplied on a Monday, it cannot be supplied again to that patient until the next Saturday) in the case of other benefits.

Exceptions to this are:

- when a PBS prescription is endorsed with the words ‘Regulation 24’ or ‘hardship conditions apply’ (see below under ‘Regulation 24’); and
- if a pharmacist believes a repeat supply is needed without delay for the treatment of the person, or a previous supply has been destroyed, lost or stolen. In this case, the pharmacist can provide another supply but must write ‘immediate supply necessary’ and sign the PBS prescription.

A pharmacist can supply an alternative pharmaceutical benefit without reference to the prescriber, provided that:
- the PBS prescription does not indicate that only the pharmaceutical benefit prescribed is to be supplied (ie substitution is not permitted); and
- the Schedule states that the prescribed benefit and the substitute benefits are equivalent; and
- supply of the substitute benefit does not contravene relevant State/Territory law; and
- the substitute benefit is a listed brand in the Schedule.

Pharmacists must heed State/Territory laws when supplying drugs listed as narcotic, specified or restricted in legislation of the particular State or Territory.

**What to do if the Schedule changes**

If an item or brand is deleted from the Schedule, it cannot be supplied as a pharmaceutical benefit from the date the deletion takes effect – regardless of whether the PBS prescription was written before this date. This includes repeat authorisations. (Special conditions applying to RPBS prescriptions are detailed in the RPBS Explanatory Notes.)

However, if restrictions on the prescribing of a pharmaceutical benefit change, or the maximum quantity or number of repeats is altered in the Schedule, valid PBS prescriptions written before the date of effect of the change may still be supplied as pharmaceutical benefits, under the conditions applying at the date of prescribing.

**Suspected forgery**

Pharmacists should take all reasonable steps to satisfy themselves that all items on a PBS prescription were written by a medical practitioner, a dentist, an optometrist, a midwife or a nurse practitioner.

**Regulation 24**

This regulation allows pharmacists to supply a pharmaceutical benefit and all of its repeats at the one time.

The PBS prescription must be endorsed by the medical practitioner, midwife or nurse practitioner with the words 'Regulation 24' if it is an item under the PBS, or 'hardship conditions apply' if it is being supplied under the RPBS. (For more information see under ‘2. Prescribing Medicines ... Regulation 24’). Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.

**Repeat authorisations**

When a PBS prescription calls for repeat supplies, the pharmacist shall prepare a Repeat Authorisation Form, except when the PBS prescription is marked ‘Regulation 24’.

The repeat may be requested on a standard PBS prescription, an authority PBS prescription or an Authority to Prescribe Form, or on an earlier repeat authorisation. In the latter case, it must come with the duplicate PBS prescription, or in the new format, the "patient/pharmacist copy".

**Preparing Repeat Authorisation Forms**

A Repeat Authorisation Form must show:

- the category of benefit (concession or general) – by placing a cross (x) in the relevant box;
- the patient’s name and full address;
- in the case of repeats authorised on authority PBS prescriptions, the authority prescription number;
- details of the original PBS prescription stating the item, form, strength, quantity and directions;
- if substitution has occurred, the name of the brand actually supplied;
- for the first supply, the pharmacy name, address and approval number, the date of the original PBS prescription and the allotted PBS prescription identifying number;
- for subsequent supplies, the pharmacy approval number, and the date and PBS prescription number of the original prescription;
- the number of times the item is to be repeated and the number of times it has been supplied;
- the name and pharmacy approval number of the pharmacist issuing the repeat authorisation; and
- the date of supply.

When a repeat authorisation is prepared for any further repeats or deferred supply, a pharmacist must attach the duplicate copy of an old format PBS prescription, or the patient/pharmacist copy of a new format PBS prescription, and give both to the patient at the time of supply.

**Repeat authorisations for deferred supply**

When a PBS prescription orders a number of pharmaceutical benefit items, but the patient does not need all of the items at the same time, a separate repeat authorisation for each deferred item must be prepared. The words 'original supply deferred' should be indicated across the relevant item on the original PBS prescription, its duplicate, and on the repeat authorisation.

Deferred items must not be claimed on the original PBS prescription.

The Repeat Authorisation Form when it is used for a deferred supply, is issued in the same way as normal repeat authorisations except that:

- '0' is to be inserted in the space for 'no. of times already dispensed'; and
- if no repeats are ordered, '0' is to be inserted in the space for 'no. of repeats authorised'.

Supplying a benefit on a deferred supply repeat authorisation is to be treated as if it is the first time of supply. If repeats are directed, the normal procedure for repeat authorisations applies. Details of the pharmacy at which the deferred supply was authorised are to be written onto subsequent repeat authorisations.
Authority PBS prescriptions

If a pharmacist is presented with an authority PBS prescription and is not sure if it has been approved, he or she should contact the Department of Human Services. Please note that the Department of Human Services will not provide clinical information.

If the authority PBS/RPBS prescription is for an Authority required (STREAMLINED) item the pharmacist should ensure that the prescriber has written the four digit streamlined authority code on the prescription, this enables the pharmacist to supply the item as a PBS benefit.

The pharmacist is required to include the four digit streamlined authority code on the claim for the PBS dispensing.

Urgent cases

In urgent cases and where State/Territory law allows, pharmacists can supply a pharmaceutical benefit to a person without a PBS prescription, provided details of the prescription are given by the prescriber via telephone or other means. The prescriber must then forward the written PBS prescription and duplicate to the pharmacist within seven days of the date of supply.

Where a pharmaceutical benefit needs prior approval from the Department of Human Services or the DVA, the prescriber must obtain approval and then advise the pharmacist of the PBS prescription and approval details. Only an original supply can be provided in this manner, not repeats.

Receipts

A person receiving a pharmaceutical benefit item must sign and date a receipt for it. If the person is not the patient, that person must also endorse the PBS prescription or repeat authorisation with his/her address. A receipt cannot be obtained until supply of the benefit has been made.

If a pharmaceutical benefit has to be sent through the post, by rail, or by other means, and a receipt is not practical, the pharmacist must certify on the PBS prescription or repeat authorisation that the benefit has been supplied, and write the date of supply and details of how it was sent. For example, if a pharmaceutical benefit is mailed to a patient on 1 April 2008, the pharmacist should write: “Certified supplied – mailed to patient 1 April 2008 (name of pharmacist) (signature of pharmacist) (date of certification)”.

If an item is supplied in an urgent case, or to a person who cannot read or write, the pharmacist should sign and date a statement on the PBS prescription or repeat authorisation, stating the item has been supplied and the date on which it was supplied, and explaining why there is no receipt. For example, if a pharmaceutical benefit is supplied to a patient with a broken arm on 1 May 2008, the pharmacist should write: “Certified supplied 1 May 2008 – patient has a broken arm and is unable to sign (name of pharmacist) (signature of pharmacist) (date of certification)”.

Only the pharmacist approved to supply pharmaceutical benefits can certify supply.

Prescriber bag supplies

Pharmacists may supply certain pharmaceutical benefit items free of charge to a PBS prescriber if they receive a prescriber bag order form in duplicate, signed by the prescriber. Only items listed under prescriber bag provisions for the relevant prescriber type can be supplied to the prescriber.

Pharmacists must be satisfied the form was completed by a PBS prescribers and includes the prescriber’s name and address. If a pharmacist does not know the prescriber, he/she should confirm the prescriber’s registration or PBS prescriber number and endorse this on the back of the form.

For more information see ‘2. Prescribing Medicines … Prescriber bag supplies’.

4. Patient Charges

Type of patient

There are two types of PBS beneficiaries, general patients, who hold a Medicare card and concessional patients who hold a Medicare card and one of the following:

- Pensioner Concession Card
- Commonwealth Seniors Health Card
- Health Care Card
- Repatriation Health Card for All Conditions (gold) — concessional patients under RPBS
- Repatiatrion Health Card for Specific Conditions (white) — only regarded as concessional patients for RPBS prescriptions unless they hold a separate entitlement from Centrelink, otherwise they are general patients
- Repatriation Pharmaceutical Benefits Card (orange) — concessional patients under RPBS
- Safety Net Concession Card or Safety Net Entitlement Card — issued by the Department of Human Services.

Concessional patients are recognised by public hospitals in all States and Territories apart from South Australia (where DVA beneficiaries are treated as general patients) and New South Wales (where holders of a white DVA card are treated as general patients).
Under the Reciprocal Health Care Agreements, visitors from participating countries (see the introduction of this section for the list of countries) are treated as general patients and do not have concessional entitlements. To receive pharmaceutical benefits these visitors may need to present a temporary Medicare card or their passport. Pharmacists should contact the Department of Human Services if they have enquiries about these arrangements.

Establishing entitlement

PBS prescription forms supplied by the Department of Human Services have spaces provided for details of a patient’s entitlement status. Anyone can enter this information, which must include:

- a cross (x) in the appropriate box to indicate the level of patient contribution;
- the complete Medicare number (including individual reference number) or complete Veteran file number on the card; and
- if applicable, the complete concession number on the card.

The person who signs the receipt for pharmaceutical benefits also accepts responsibility for the validity of the entitlement information on the PBS prescription.

All PBS prescriptions must have a Medicare or Veteran file number. All concessional PBS prescriptions must have a concession number. However, it is not necessary for the Medicare or Veteran file number, or the concession number to be endorsed on the PBS prescription if it is included in the electronic prescription details supplied by a pharmacist who is using the Claims Transmission System.

What to charge

Patient contribution

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is $37.70 for general patients and $6.10 for concessional patients, plus any applicable special patient contribution, brand premium or therapeutic group premium. General patients who have reached the safety net threshold (see details under ‘5. The Safety Net Scheme’) may receive pharmaceutical benefits at the concessional rate, plus any applicable special patient contribution, brand premium or therapeutic group premium.

Patients who have a Safety Net Entitlement Card (see details under ‘5. The Safety Net Scheme’) may receive PBS items free of charge, except for any applicable special patient contribution, brand premium or therapeutic group premium.

The contribution rate for general patients as outpatients at public hospitals in most of Australia is $30.20. The exceptions are in hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item listed in the Schedule (see details under ‘5. The Safety Net Scheme’), or up to the general co-payment amount for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the PBS to outpatients and patients upon discharge. A range of chemotherapy drugs is also available for day-admitted and non-admitted chemotherapy patients.

The contribution rate for concessional patients in all public hospitals is equal to the concessional co-payment amount.

The supply of a pharmaceutical benefit or a Repatriation pharmaceutical benefit to a patient is GST-free. Goods and services tax must not be included in the price charged to a patient for the supply of a PBS or RPBS script.

It is the patient’s responsibility to pay any charge lawfully imposed by an approved pharmacist or supply may be refused.

The patient contribution rates are adjusted on 1 January each year in line with inflation.

Patient contributions for early supply of some PBS medicines

Prescriptions for some PBS and RPBS pharmaceutical benefits are not eligible for safety net benefits if re-supplied within 20 days of a supply of the same pharmaceutical benefit for the same person. This is known as the ‘Safety Net 20 day rule’ and came into effect on 1 January 2006.

Where a prescription is subject to the Safety Net 20 day rules:

- the patient contribution does not count towards the Safety Net, and
- after the Safety Net threshold is reached, the usual patient co-payment amount for the corresponding entitlement level (not the Safety Net amount) applies.

For example: The payment for such a prescription for a patient with a Safety Net Entitlement Card would be the concessional co-payment amount — not free. For a general patient with a Safety Net Concession Card, the usual general co-payment amount would apply — not the concessional amount.

The Safety Net 20 day rule does not apply to PBS/RPBS prescriptions originating from hospitals or day hospital facilities.

Special patient contributions, brand premiums and therapeutic group premiums

A special patient contribution is payable for a pharmaceutical benefit when a supplier will not supply it at the benchmark price. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Other than for bleomycin sulfate (available under the ‘Efficient Funding of Chemotherapy - Section 100 Arrangements’), exemptions on medical grounds are available, but must be granted by the Department of Human Services. For RPBS special patient contribution arrangements see the RPBS Explanatory Notes.

Under the brand premium arrangements, reimbursement to pharmacists is based on the lowest-priced brand. Any extra charge for a higher priced brand is paid by the patient, together with their usual patient contribution.
Under the therapeutic group premium arrangements, reimbursement to pharmacists is based on the lowest priced benefit items within identified therapeutic groups. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Exemptions on medical grounds are available, but must be granted by the Department of Human Services.

Special patient contributions, brand premiums and therapeutic group premiums apply to maximum quantities. When a quantity is less than, or — on an authority or ‘Regulation 24’ PBS prescription — more than, the maximum, the contributions or premiums will be a factor of the maximum quantity, using standard pricing rules.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

**Increased quantities**

Where a prescriber has written an authority PBS prescription for a quantity greater than the maximum, the patient contribution should be made for each supply of the increased maximum quantity.

**Regulation 24**

For ‘Regulation 24’ PBS prescriptions, a pharmacist should charge the usual patient contribution for the original and for each repeat quantity needed to make up the total supply (plus any applicable special patient contribution, brand premium or therapeutic group premium, for the original and each repeat quantity in the total supply).

**After hours**

A pharmacist may charge an extra fee if supplying a PBS item outside normal trading hours. This charge is paid by the patient and does not count towards the safety net.

**Delivery**

A charge can be added for delivering pharmaceutical benefits from the pharmacy. This charge does not count towards the safety net. For RPBS delivery arrangements refer to the RPBS Explanatory Notes.

## 5. The Safety Net Scheme

The PBS safety net protects patients and their families requiring a large number of PBS or RPBS items. For the purposes of the scheme, the family includes the person:

- the partner or de facto partner;
- children under the age of 16 who are in the care and control of the person; or
- dependent full-time students under the age of 25.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

The safety net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals. Pharmaceutical benefits (including authority items) can only be counted towards the safety net threshold when prescribed and supplied according to PBS conditions. A medicine supplied by a pharmacist not approved to supply pharmaceutical benefits cannot count towards the safety net.

Prescriptions for some pharmaceutical benefits are not eligible for safety net arrangements if re-supplied within 20 days of supply of the same item for the same person and the patient contribution cannot count towards the safety net (see also details under ‘4. Patient Charges’ and ‘7. How Pharmacists Claim Reimbursement’). This does not apply to out-patient medications in public hospitals or to any prescriptions originating from a hospital or day hospital facility.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

**Safety net thresholds**

There are two safety net thresholds. The general patient safety net threshold is currently $1,453.90. When a person and/or their family’s total applicable co-payments reach this amount, they may apply for a safety net concession card and pay the concessional co-payment amount of $6.10 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.
The concessional safety net threshold is $366.00 (this also applies to gold, white or orange card holders under the RPBS). When a patient and/or their family's total applicable co-payments reach this amount, they may apply for a safety net entitlement card and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.

Brand premiums, therapeutic group premiums and special patient contributions do not count towards the safety net thresholds.

The safety net thresholds are adjusted on 1 January each year in line with inflation.

**Safety net cross-over arrangements**

Some patients and/or members of their families will change between general patient and concessional patient status during a calendar year. Patients should apply for the safety net card appropriate to their status at the time they apply.

Concessional patients who were previously general patients can apply for a safety net entitlement card when they reach the concessional safety net threshold. In this case, any pharmaceutical benefits previously supplied at the general co-payment rate in that calendar year will be counted at the concessional rate per item.

General patients who were previously concessional patients can apply for a safety net concession card when they reach the general safety net threshold. In this case, any pharmaceutical benefits previously supplied at the concessional rate in that calendar year will be counted at the concessional rate per item.

In the case of families where one parent holds a concession card and other family members are general patients, the family can choose to apply for either a safety net entitlement card or a safety net concession card.

To receive a safety net entitlement card, all pharmaceutical benefits (including general pharmaceutical benefits) are counted at the concessional rate per item until the concessional threshold is reached. To receive a safety net concession card, general pharmaceutical benefits are counted at the general co-payment rate per item and concessional pharmaceutical benefits at the concessional rate per item, until the general safety net threshold is reached.

White DVA card holders may either be general or concessional patients (depending on their Centrelink entitlements). If they are receiving treatment for a specific disability accepted by the DVA, they are also supplied with specified items under the RPBS at the concessional rate per item. Therefore, these patients are encouraged to maintain a concessional prescription record form, plus a general prescription record form for items not covered under the RPBS.

White card holders may choose at any time to count contributions made at the general level towards the concessional safety net threshold and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased. Alternatively, white card holders can count contributions at the concessional level towards the general safety net, and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased.

Gold or orange DVA card holders may receive all of their prescription items under the RPBS, and only pay the concessional co-payment amount for each item.

Dependants of white, gold or orange card holders are treated separately and may be either general patients or concessional patients. Their prescriptions may be included in the cross-over arrangements.

**Recording PBS prescriptions**

There are two types of prescription record forms to record PBS prescription items. A blue form, used for items obtained at community pharmacies and available from community pharmacies, Medicare Service Centres and the Department of Human Services; and a grey form, used by out-patients who pay for items at public hospital pharmacies and available from hospital out-patient departments or the Department of Human Services.

Patients should record their general or concessional status on the prescription record form, enter their Centrelink, DVA and/or Safety Net Concession/Entitlement Card number, and list family members covered. General patients must also record their Medicare number when applying for a safety net concession card.

Details to be entered on the form by the pharmacist are:

- date of supply;
- PBS/RPBS code number of the item (for community pharmacies only);
- the safety net value of the item (for community pharmacies only);
- pharmacist’s approval number (for community pharmacies only);
- item identification — medicine code, name of medicine or abbreviation (for public hospitals only);
- hospital charge (for public hospitals only);
- hospital safety net number (for public hospitals only); and
- signature of the authorised person making the entry.

Community pharmacists should record in the ‘safety net value’ column:

- the patient contribution when it is less than the PBS dispensed price; or
- the safety net value shown in the Schedule, or any lesser amount charged, if the PBS dispensed price is less than or equal to the patient contribution. The pharmacist may discount the price for these items.

Some computer software suppliers provide a special label to record this information on the prescription record forms. Some suppliers also provide a computer printout as a prescription record form.
The patient is responsible for maintenance and storage of their prescription record form. However, it may be kept in the pharmacy. A person (or family) may have more than one prescription record form.

**Hospital prescription record forms**

Items to be recorded on hospital prescription record forms must be approved by the hospital’s pharmaceutical advisory committee and may be listed on a hospital’s formulary (a list of pharmaceutical items approved by the committee for the treatment of particular illnesses), or authorised on a patient-by-patient basis.

**Multi-item prescription forms**

If a patient submits a multi-item PBS prescription form, which would take the total co-payments past the safety net threshold, any items in excess are treated as entitled items once a safety net entitlement/concession card is issued.

Excess items should be treated as ‘deferred supply’ items.

For example, if a family has a new PBS prescription for three items and the first takes the family up to the threshold, then this item should be supplied at the general rate. If the second item takes the family over the threshold, the pharmacist should then issue a safety net concession card and supply both this and the third item at the concessional rate. This involves the deferral of two items, recording the safety net concession card number, and the subsequent supply of these items.

**Qualifying PBS prescriptions**

A PBS prescription should be supplied at the concessional rate or free of charge plus any applicable premium, when the safety net value or hospital charge for that PBS prescription takes the total co-payments over the qualifying amount for a safety net entitlement/concession card.

**Lost prescription record forms**

If a prescription record form has been lost, stolen or destroyed, a pharmacist may prepare a duplicate copy, but is under no obligation to do so.

**Retrospective entitlement and patient refunds**

Responsibility for claiming entitlements rests with the patient. If items recorded on a prescription record form have exceeded the safety net threshold, the cost of those items in excess of the limit cannot be refunded by a pharmacist.

However, if the patient failed to apply for a safety net entitlement/concession card on reaching the safety net threshold they should write to the Department of Human Services and provide copies of pharmacy accounts or a signed statement from the pharmacist giving the date of supply, description and cost of items supplied and paid for. A copy of the relevant prescription record form should also be provided. If these are not available, the patient should give the name of the pharmacy where the card was issued and the number on the card so that the Department of Human Services can locate the prescription record form in its records. Cash refunds are not available. The Department of Human Services contact details are provided in the ‘Addresses — Department of Human Services’ part of the Schedule.

If the patient cannot satisfy a pharmacist that they have a current entitlement and is charged the general patient price, the pharmacist should issue the patient with a receipt and a claim form (provided by the Department of Human Services). The patient can then obtain a refund via Medicare Service Centres or PBS processing centres. RPBS prescription refunds are paid at DVA State offices.

The Department of Human Services can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the safety net concessional or safety net entitlement amount as a result of the safety net 20 day rule. Receipts for prescriptions where the safety net 20 day rule has applied must include ‘SN20DR’ to indicate the reason for the amount charged.

There are separate arrangements for PBS prescriptions in some public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

**Applying for a Safety Net Entitlement/Concession Card**

Once the safety net threshold has been reached, the person covered by a prescription record form may complete the application and declaration to get a safety net entitlement/concession card. Please note that software packages that produce computer generated applications must be approved by the Department of Human Services.

If the card is issued to a dependent child or student, it should be in the name of a parent.

When issuing entitlement/concession cards, pharmacists do not have to check all prescription record form details. However, they should ensure each entry has been signed and that the prescription record form total qualifies the patient for the relevant safety net card.

When appropriate the pharmacist should check that the patient’s Medicare card number is on the prescription record form.
Issuing a Safety Net Entitlement/Concession Card

When satisfied that the individual or family is entitled, the pharmacist should issue the next blank safety net entitlement/concession card with the following details:

- the names of family members covered. If there are more than eight family members, a second card should be issued listing the card holder and family members not listed on the first card. The prescription record form has space to record that two cards have been issued, and
- the two-character code to indicate the relationship to the card holder. Applicable codes are:
  - SP - partner;
  - DC - child under 16 years; and
  - DS - dependent full-time student under 25 years.

The pharmacist should be satisfied that only family members are listed on the card. The unused space on the card should be ruled through to prevent extra names being added. The sticky label from the safety net entitlement/concession card, pre-printed with the card number, should be attached to the prescription record form. The pharmacist should sign and stamp each prescription record form with the pharmacy stamp and enter the card issue details on a safety net — claim for payment form.

Issuing supplementary cards

A pharmacist may give a card holder a supplementary card for a partner or dependant only at the time the original card is issued. The duplicate card should be recorded in the additional box on the prescription record form.

Later requests for supplementary cards and requests to add a new family member to the original card are to be referred to the Department of Human Services.

Notification to the Department of Human Services and claim for payment

Payment for issuing a safety net entitlement/concession card is made after the safety net — claim for payment form is sent to the Department of Human Services, no later than one month after a card is issued.

Each form must be accompanied by all supporting documentation (prescription record form and cancelled or void safety net entitlement/concession cards).

Payment will not be made for void cards.

Lost Safety Net Entitlement/Concession Cards

When a card has been lost, damaged, stolen or destroyed, a pharmacist cannot re-issue a person with a replacement card. The original card holder (or partner) must apply to the Department of Human Services.

Pharmacy record of issued cards

A record of all cards issued must be kept at the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits. The duplicate ('bookfast') copy in the safety net — claim for payment book is provided for this purpose.

6. Department of Human Services Entitlement Checks

General Patients

The Department of Human Services validates a patient’s entitlement to pharmaceutical benefits by checking the Department of Human Services and/or Veteran file numbers in pharmacist’s claims. If a number is not recorded correctly, a patient cannot be identified against the Department of Human Services’ Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

If the Medicare or Veteran file number provided in the pharmacists’ claims is incorrect or the number and the name supplied do not match the Department of Human Services records to enable patient identification, an appropriate warning or rejection code will be returned to the pharmacy. These notifications of missing or incorrect Medicare or Veteran file numbers are provided to pharmacists in their reconciliation statement produced after the claim period has been paid by the Department of Human Services.

Special numbers are available for use in certain circumstances for eligible people who are unable to provide a Medicare number.

Concessional Patients

The Department of Human Services routinely validates a patient’s entitlement to free or concessional benefits by checking concessional numbers in pharmacists’ claims. If a number is not recorded correctly, a patient cannot be identified against the Department of Human Services’ Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

When a number is found to be from a card which was incorrect, expired at the time of supply or entitlement was withdrawn, warning or rejection codes will be returned to the pharmacy to assist with validation of concessional entitlement in relation to future claims from the same patient.
Entitlement checking procedures

General Patients

Once a pharmacist has been notified by the Department of Human Services of an incorrect Medicare or Veteran file number he/she should correct the number for future claims by:

- updating his/her system to reflect the correct number provided by the Department of Human Services (if patient consent to do so has been obtained); or
- speaking to the patient; or
- obtaining patient consent and calling the Department of Human Services on the Improved Monitoring of Entitlements (IME) (132 290 — select option 1).

If the patient presents a Medicare card that appears correct, but according to the Department of Human Services is not a valid number, or not a valid number for that person, a pharmacist may use a special number. A photocopy of the card, or a form must accompany the use of this number. The form is available on the Department of Human Services’ website or by calling 132 290.

Concessional Patients

Once a pharmacist has been notified by the Department of Human Services of an incorrect concessional entitlement number, he/she should view the entitlement card to confirm the entitlement number, and start and end dates, when the patient next presents a PBS prescription.

Step by step

Pharmacists should take the following steps where concession entitlement does not appear to be valid or current:

- Re-confirm entitlement with the cardholder/customer;
- Contact the Department of Human Services on 132 290, with consent, to confirm the cardholder/customer concession status;
- If the Department of Human Services advises that the cardholder/customer is concessionally entitled to receive the PBS medicines on that day, supply the prescription as a concessional entitlement;
- If the Department of Human Services advises that the cardholder/customer is not concessionally entitled to receive the PBS medicines on that day, supply as a general prescription. Provide the customer with the information sheet “Your entitlement card” which explains entitlement checking to the customer and the steps they can follow if they are concessionally entitled.


The Department of Human Services uses a computerised system for pricing PBS prescriptions, repeat authorisations and prescriber bag supply orders, and for calculating claims.

The payment system is designed to pay pharmacists correctly for the pharmaceutical benefits they supply. It is essential instructions are followed carefully and that each document includes all relevant information. Accurate and complete data ensures claim payment is not delayed.

PBS Prescription identification

Pharmacists must include certain information on each PBS prescription sent in for claim, as specified below. It is important that this information is entered correctly and in the right place on the PBS prescription. This information will be included in a sticker produced by pharmacy software.

The sticker should be placed on the extreme left front of a PBS prescription, opposite each item being claimed. It must not obscure any details written by the prescriber. Most prescribers use PBS prescriptions, which have space for the sticker. If a sticker is not used, a PBS prescription identification stamp can be used or the information can be written in the same place, and in the same order.

Pharmacists should avoid writing over, or placing the sticker over, the prescriber number pre-printed on PBS/RPBS prescriptions, or the prescriber number box on PBS dental and optometrist, midwife and nurse practitioner prescriptions.

The sticker is not necessary for current repeat authorisation, prescriber bag supplies, or for old style authority PBS prescription and authority to prescribe forms, as they have printed spaces for the necessary details. However, it is required for the new format authority PBS prescription forms.

The following information should be entered next to the appropriate letter on the sticker or stamp:

- ‘S’ — the serial number for the claim
- ‘A’ —
  - the price claimed for pricing elected PBS prescriptions, exceptional PBS prescriptions and RPBS non-scheduled prescriptions (see under ‘Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List’ for explanations of pricing elected PBS prescriptions and exceptional PBS prescriptions); and/or
  - confirmation that the PBS prescription is endorsed ‘Regulation 24’ or the RPBS prescription is endorsed ‘hardship conditions apply’; and/or
  - a claim for a glass dropper bottle where applicable; and/or
  - any clarification of the prescription which will assist the Department of Human Services payment processing.
- ‘No.’ — the PBS prescription identifying number.
Serial numbers

PBS prescription, repeat authorisation, authority PBS prescription, and prescriber bag order forms submitted in each claim must bear consecutive serial numbers starting with:

- 1 – for prescriber bag supplies;
- 1 – for general benefits;
- C1 – for concessional and Safety Net Concession Card benefits;
- E1 – for Safety Net Entitlement Card benefits; and
- R1 – for RPBS benefits.

Each serial number should also be noted on any document kept by the pharmacist for record purposes.

Each prescriber bag item should be given a serial number, e.g., if there are five items on the first form in the claim, the first item on the second form in the claim will start with the serial number 6.

For prescriptions subject to the Safety Net 20 day rule, the serial number corresponds to the resulting payment category for the pharmaceutical benefit as supplied, not the patient’s entitlement category.

Repeat authorisations for authority PBS prescriptions

When a benefit is supplied on a repeat authorisation which needed an authority PBS prescription, the serial number must be prefixed with the letter ‘A’ for a general benefit; ‘AC’ for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; ‘AE’ for a Safety Net Entitlement Card holder; or ‘AR’ for a RPBS benefit.

Repeat authorisations for deferred supply

When a benefit is supplied on a repeat authorisation prepared for deferred supply, the serial number must be prefixed with the letter ‘D’ for a general benefit; ‘DC’ for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; ‘DE’ for a Safety Net Entitlement Card holder; or ‘DR’ for a RPBS benefit.

Dropper containers

Dispensed prices for extemporaneously-prepared eye drops, ear drops and nasal instillations include the price of a polythene dropper container. However, if a glass dropper container is supplied, payment should be claimed by writing ‘glass bottle’ in box ‘A’ of the stamp.

Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List

When a formula is not listed on the Standard Formulae List, the PBS prescription is paid at an average of 10 g/mL rate for the type of preparation, unless the pharmacist elects otherwise. A pharmacist may price an exceptional PBS prescription, or elect to price all non-pre-priced extemporaneous PBS prescriptions.

PBS prescriptions paid on an average price basis

If the PBS prescription is to be claimed as an exceptional PBS prescription, the pharmacist should write details of the formula supplied on the PBS prescription or repeat authorisation form; price the PBS prescription in accordance with the pricing principles (as detailed in ‘9. Pricing PBS Prescriptions’); and enter the calculated price on the sticker.

An exceptional PBS prescription is for an extemporaneously-prepared pharmaceutical benefit that is not included in the Standard Formulae List and for which the price of the ingredients (based on basic pricing rules) is twice or more than the recovery price of the ingredients calculated on an average price basis. Further information on pricing PBS prescriptions can be accessed from the book let titled Explanation of Current Pricing on the Department of Human Services’ website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

Pricing non-pre-priced extemporaneous preparations

Pharmacists should notify the Department of Human Services when they elect to price non-pre-priced extemporaneous preparations. Each PBS prescription should be priced in accordance with the pricing principles and that price entered on the sticker.

RPBS prescriptions for items not included in either the PBS or RPBS Schedule

When a prescription for a RPBS patient is for an item not included in either the PBS or the RPBS Schedule, the price claimed should be entered on the sticker. Full details on pricing and availability of such items under the RPBS are set out in the RPBS Explanatory Notes.

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

Premium Free Dispensing Incentive payments will commence for eligible PBS listed products dispensed from 1 August 2008. Premium Free Dispensing Incentive payments will be available to approved suppliers to dispense a substitutable, premium-free medicine. The payment will be available only for PBS items which attract a Government subsidy. This includes PBS items supplied to DVA entitled consumers.

A number of conditions and criteria apply to receive this payment. Scripts will be assessed for validity and the Premium Free Dispensing Incentive payment will be paid by the Department of Human Services. Further information on this payment can be found on the Department of Human Services’ website at:

www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.jsp#dispensing
8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

1. the original and duplicate of a completed Claim for Payment Form;
2. the original orders for prescriber bag supplies in a separate bundle;
3. the originals of all old format PBS prescriptions and authority PBS prescriptions, the Department of Human Services/DVA copies of new format PBS prescriptions and authority PBS prescriptions, and all repeat authorisations, separated into four bundles for benefits supplied to the general public; concessional beneficiaries/Safety Net Concession Card holders; Safety Net Entitlement Card holders and RPBS patients.

In order to satisfy auditing/spot check compliance measures, PBS prescriptions in each bundle should be in serial number order, with serial number 1 at the top of the bundle.

PBS prescriptions subject to the Safety Net 20 day rule are bundled according to the resulting payment category. For prescription forms with multiple PBS items, where the Safety Net 20 day rule would result in different payment categories for different items, dispensing via ‘deferred supply’ should be used where necessary to allow all items to be included in the correct bundles.

PBS prescriptions in the wrong bundle may be returned to the pharmacist for clarification. If appropriate, they can be resubmitted in the correct bundle in the next claim period.

Completing the claim form

The claimant’s name, address of the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits, approval number, and claim period number should be entered on the Claim for Payment Form. These details should match the latest written information held by the Department of Human Services, or payments can be delayed while clarification is sought.

The claim period number should state how many claims have been submitted so far in a calendar year, e.g., the sixth claim submitted by an approved pharmacist in 2005 should have a claim period number of 0506.

The first and last serial numbers given to items in each bundle are to be entered on the Claim for Payment Form.

A total claim amount is not required – this will be calculated by the Department of Human Services after the PBS prescriptions have been individually priced.

The declaration must be signed by the pharmacist approved to supply pharmaceutical benefits, unless he/she has made arrangements through the Department of Human Services for another pharmacist to sign it.

Lodging claims

A claim may be lodged at any time during the month at the relevant Department of Human Services State office. Unless other arrangements have been made with the Department of Human Services, the following conditions apply:

- only one claim period can exist and only one claim can be lodged per month;
- the claim period shall cover pharmaceutical benefits supplied during one month; and
- the claim shall be sent within 30 days from when the benefits were supplied.

Claims for pharmaceutical benefits supplied over 18 months earlier may not be accepted for computer processing. Pharmacists with such claims should contact the Department of Human Services.

Reconciliation statements

As mentioned earlier, a pharmacist will receive a PBS reconciliation statement after a claim period has been processed. It provides details of each prescription for each brand of each pharmaceutical benefit item supplied in that claim period.

Reasons for non-payment of any item are coded, with the code numbers explained in the statement.

PBS prescriptions and repeat authorisations not accepted for payment will be returned, with the exception of PBS prescriptions with a dispensed price equal to or less than the patient contribution. Any other items on those PBS prescriptions that have been paid will have been cancelled.

If a PBS prescription was not accepted and can be re-submitted, it must be given a new serial number and included in a subsequent claim period.

If a PBS prescription is finally rejected for payment and a pharmacist is not satisfied with the decision, he/she may apply to the Administrative Appeals Tribunal for a review of that decision.

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

For ready-prepared pharmaceutical benefits, payment is made on the basis of the lowest-priced brand.
For a pharmaceutical benefit not listed as a ready-prepared item, and where a formulation title is stated but no formulary specified, payment is made on the basis of precedence given to formularies by State/Territory legislation.

Prices published in the Schedule do not include any component for goods and services tax (GST).

Further information on pricing PBS prescriptions can be accessed from the booklet titled *Explanation of Current Pricing* on the Department of Human Services' website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

**Pricing dates**

Ready-prepared pharmaceutical benefits are priced on the first day of April, August and December for items supplied as from each of those days respectively.

Extemporaneously-prepared pharmaceutical benefits and containers are priced on the first day of May each year for items supplied as from the first day of August that year.

**Pricing ready-prepared items**

*For maximum quantities*

The price payable for a pharmaceutical benefit is shown in the Schedule against the item. The price is for the maximum quantity available.

The maximum quantity of some pharmaceutical benefits, such as eye drops and oral suspensions, has been determined as a single pack corresponding to the manufacturer’s pack. These packs cannot be broken, so if a PBS prescription calls for less, the maximum quantity should be supplied and claimed from the Department of Human Services. Packs not to be broken are indicated by a double dagger (‡) in the Schedule.

*For lesser quantities*

For items where the standard pack is the same as the maximum quantity, and the pack can be broken, the price payable for a lesser quantity is established as follows:

- an amount equal to the dispensing fee, and if applicable the dangerous drug fee, is deducted from the benefit price as shown in the Schedule;
- to this new amount, a wastage percentage is applied, determined from the Wastage Factor Table;
- then the amount equal to the dispensing fee, dangerous drug fee (if applicable), and appropriate container fee, is added.

In no case shall the price for a broken quantity be more than the dispensed price of the Schedule’s maximum quantity.

When a standard pack is not the same as the maximum quantity, the price of the pharmaceutical benefit concerned has an asterisk next to it and the standard pack rate is set out in Section 3 of the Schedule. The price payable for the quantity supplied is established by:

- applying the appropriate wastage table percentage to the standard pack rate;
- then adding an amount equivalent to the dispensing fee, the dangerous drug fee where applicable, and the appropriate container fee.

In no case shall the supply of a broken quantity, which is less than the item’s maximum quantity, cost more than the dispensed price for the maximum quantity.

No container fee is payable when the quantity of pharmaceutical benefit supplied is more than the quantity contained in the standard pack.

**Wastage table percentage**

The following Wastage Factor Table is used to calculate the price payable for quantities supplied from the standard pack.

**Wastage Factor Table**

| Column A | 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 |
| Column B | 10, 18, 26, 32, 38, 44, 50, 54, 58, 62, 66, 70, 74, 78, 82, 86, 90, 94, 98, 100 |

The appropriate wastage table percentage is as follows:

1. the percentage of the amount supplied from the amount in the standard pack is determined; and
2. where this percentage is the same as a percentage listed in Column A of the table, the percentage used is the figure shown in Column B; or
3. where the percentage is not the same as a percentage in Column A, then the nearest upward percentage in Column A applies, and the percentage used is the figure in Column B.

For example, 24 tablets are supplied from a standard pack of 100. Thus 24 per cent of the number contained in the standard pack is supplied. As this percentage does not appear in Column A, the next higher (i.e., 25 per cent) is used. Reading down from 25 per cent to Column B, the wastage table percentage is found to be 38 per cent.

**Pricing extemporaneously-prepared items**

*General*

The price payable for supplying the maximum quantity of standard formula preparations is shown in the Standard Formulae List.
The following principles apply in determining prices of all pre-priced extemporaneous formulae on the list.

They also apply when a pharmacist elects to price extemporaneous PBS prescriptions outside the list, including exceptional PBS prescriptions.

The amount payable is the sum of:

- the recovery price of each ingredient as shown in the Drug Tariff;
- the price of the appropriate container as shown in the price section; and
- a dispensing fee as shown in the price section.

**Pricing of ingredients**

When the quantity dispensed is not specified in the Drug Tariff, the recovery price is as follows:

1. determine the basic pricing unit relative to the quantity dispensed by referring to the following table:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Basic Pricing Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to and including 700 mg</td>
<td>100 mg price rate</td>
</tr>
<tr>
<td>Over 700 mg and up to and including 1 g</td>
<td>price as if 1 g</td>
</tr>
<tr>
<td>Over 1 g and up to and including 7 g</td>
<td>1 g price rate</td>
</tr>
<tr>
<td>Over 7 g and up to and including 10 g</td>
<td>price as if 10 g</td>
</tr>
<tr>
<td>Over 10 g and up to and including 80 g</td>
<td>10 g price rate</td>
</tr>
<tr>
<td>Over 80 g and up to and including 90 g</td>
<td>price as if 80 g</td>
</tr>
<tr>
<td>Over 90 g</td>
<td>100 g price rate</td>
</tr>
</tbody>
</table>

2. find the recovery price of the basic pricing unit by applying the following quantity divisors to the recovery price shown for the ingredient in the Drug Tariff:
   - 100 g price is 500 g price divided by 5, or 1 kg price divided by 10
   - 10 g price is 100 g price plus 12.5 per cent divided by 10
   - 1 g price is 10 g price plus 25 per cent divided by 10
   - 100 mg price is 1 g price plus 25 per cent divided by 10

3. find the recovery price by multiplying the price of the basic pricing unit – as established in 2 – by the fraction that the quantity dispensed bears to the basic pricing unit.

For pricing purposes the quantity is to be taken to the next upward 50 milligrams or 0.05 millilitres.

The minimum recovery price for any ingredient is one cent. In other cases where a fraction of a cent occurs, the price is to be taken to the nearest cent (a half cent being taken up to the next cent).

In no case shall the recovery price for a quantity of an ingredient exceed the recovery price for a greater quantity of that ingredient.

Where liquids are purchased by weight, the recovery price includes the ‘Specific Gravity Factor’.

Special pricing provisions apply to drugs marked ‘(a)’ or ‘(b)’ in the Drug Tariff.

For drugs marked ‘(a)’, the pricing rules shown above apply to quantities up to the quantity listed in the Drug Tariff. Greater quantities are priced on a linear basis: the recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff by the price shown for the quantity listed.

Drugs marked ‘(b)’ are packed sterile or are unstable, and all quantities are priced as if whole pack(s) were required. The recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff, taken to the next whole number, by the price shown for the quantity listed.

**Pricing PBS prescriptions where extra ingredients are added to a formula**

Where the vehicle is liquid and one or more solid ingredients are added, displacement of the liquid by the solid ingredients is disregarded for pricing purposes.

**Containers**

When a quantity is for more than the container sizes listed in this Schedule, payment will be made as if that quantity had been supplied in the minimum number of containers necessary to supply that quantity.

A double size container is allowed for bulk powders.

**Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List**

If a pharmacist elects to price extemporaneous PBS prescriptions outside the Standard Formulae List, there can be no variation for three months. This applies to all extemporaneously-prepared formulae not on the list, and includes both PBS and RPBS prescriptions.
If a pharmacist does not elect to price out these PBS prescriptions, he/she will be paid at an average reimbursement rate.

Under this system, payment is made on the basis of an average 10 g/mL rate applied to the category of preparation concerned, i.e., the price will be determined by multiplying the appropriate 10 g/mL rate by the number of 10 g/mL units supplied and adding container and dispensing fees. For example, an 80 mL mixture would be priced at eight times the average 10 mL rate for mixtures, with container and dispensing fee added.

The average 10 g/mL rate for each type of preparation is calculated monthly. It applies to PBS prescriptions supplied in the following month.

PBS prescriptions ordering a combination of standard formula preparations fall outside the scope of the Standard Formulae List and therefore are subject to this section.

Any variant to a formula included in the list (adding or deleting an ingredient or varying the dose) takes the formula dispensed outside the list. When an ingredient is added to a standard formula and the recovery price for the standard formula plus additive under the average price system is less than for the standard formula alone, the pharmacist may have the PBS prescription priced as a basic standard formula item.

10. Miscellaneous

References

This Schedule identifies monographs of the British Pharmacopoeia, the British Pharmaceutical Codex, and the Australian Pharmaceutical Formulary and Handbook by the letters BP, BPC and APF respectively. References to all editions of the BPC and to earlier editions of the BP and APF also include the year of publication or the number of the edition.

Standards

Pharmacists can only supply under the PBS medicines which, or whose ingredients, conform to the standards of composition or purity prescribed. These standards are those specified in the Therapeutic Goods Act 1989.

Legislation

Copies of the National Health Act 1953 and the National Health (Pharmaceutical Benefits) Regulations 1960 are available from Government AusInfo shops in each capital city. The Act and the Regulations may also be accessed through the Attorney-General’s Department website at www.comlaw.gov.au.

Nurse practitioner PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED NURSE PRACTITIONERS

From 1 September 2010, nurse practitioners endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (authorised nurse practitioners). Information for nurse practitioners to become authorised PBS prescribers is available from the Department of Human Services.

The medicines listed for prescribing by authorised nurse practitioners from 1 November 2010 are identified by ‘NP’ in the PBS Schedule. Nurse practitioners must not write PBS prescriptions for other medicines.

PBS prescribing is limited by a nurse practitioner’s scope of practice, and state and territory prescribing rights. Prescribing of PBS medicines is also contingent on a prescriber being an authorised nurse practitioner and having collaborative arrangements in place, as required by amendments to the National Health Act 1953.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health regarding medicines for prescribing by authorised nurse practitioners.

Further to prescribing within collaborative arrangements, certain medicines also have additional conditions for prescribing by nurse practitioners, as recommended by the PBAC. These medicines are identified by the codes ‘CTO’ for continuation therapy only or ‘SCM’ for prescribing within a shared care model, as outlined below:

- **Continuing therapy only model**
  Where the patient’s treatment and prescribing of a medicine has been initiated by a medical practitioner, but prescribing is continued by a nurse practitioner. (This is similar to existing arrangements between specialists and medical practitioners for prescribing certain medicines.)

- **Shared care model**
  Where care is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed plan to manage the patient, in a patient-centred model of care. The details surrounding shared care arrangements will depend on the practitioners involved, patient needs and the healthcare context.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.
Nurse practitioner PBS prescriptions are identifiable by colour, and include the indicator ‘NP’ on personalised forms and a tick box on non-personalised (blank) forms.

Prescriptions must include the nurse practitioner’s PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined) PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Nurse practitioner PBS prescriptions may include repeats.

Regulation 24 applies for nurse practitioner prescribing. A nurse practitioner can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and territory requirements: Nurse practitioners may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the nurse practitioner’s responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

**Midwife PBS prescribing**

**MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED MIDWIVES**

From 1 September 2010, midwives endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (authorisedmidwives). Information for midwives to become authorised PBS prescribers is available from the Department of Human Services.

The medicines listed for prescribing by authorised midwives are identifiable by ‘MW’ in the PBS Schedule. Midwives must not write PBS prescriptions for other medicines.

PBS prescribing by midwives is limited by state and territory prescribing rights. It is also contingent on a prescriber being an authorised midwife and having collaborative arrangements in place, as required by amendments to the National Health Act 1953.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health regarding medicines for prescribing by authorised midwives.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Midwife PBS prescriptions are identifiable by colour, and include the indicator ‘MW’ on personalised forms and a tick box on non-personalised (blank) forms. Prescriptions must include the midwife’s PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined) PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Midwife PBS prescriptions may include repeats.

Regulation 24 applies for midwife prescribing. A midwife can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and territory requirements: Midwives may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the midwife’s responsibility to ensure adherence to state/territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

**Optometrist PBS prescribing**

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS**

From 1 January 2008, optometrists accredited to prescribe under State or Territory legislation can apply for approval as PBS prescribers (authorised optometrists). Information for optometrists on becoming a PBS prescriber is available from the Department of Human Services.

The medications listed for prescribing by authorised optometrists are identified by ‘OP’ in the PBS Schedule. Optometrists must not write PBS prescriptions for any other medicines listed on the PBS.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health regarding preparations for prescribing by authorised optometrists.

Some products are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their practitioner type.
Optometrist PBS prescriptions are identifiable by colour, and include the words ‘PBS/RPBS optometrist’. Prescriptions must include the optometrist’s PBS prescriber number. The same optometrist prescription form is used to prescribe unrestricted, restricted or authority items. Only one item is allowed per form. Optometrist PBS prescriptions may include repeats.

Regulation 24 does not apply for optometrist prescribing. An optometrist cannot direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time.

**Authority prescriptions:** Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services or the Department of Veterans’ Affairs (DVA) for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.) DVA approval for non-Schedule items is not available for optometrist prescribing.

**RPBS:** Optometrists approved as PBS prescribers may write prescriptions for supply under the RPBS. The medicines available for prescribing by authorised optometrists under the RPBS are the same as those available under the PBS. There are no optometrist listings in the Repatriation Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS Schedule (non-Schedule items).

**State and Territory requirements:** Optometrists may prescribe medications as private prescriptions according to their State/Territory prescribing accreditation. The medicines which can be prescribed differ between States and Territories. It is the optometrist’s responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS/RPBS prescriptions.

**GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS**

Under these guidelines, authorised optometrists who are approved to use therapeutic drugs in their practices and who have adequate professional indemnity cover, will be able to co-manage glaucoma patients in a shared care arrangement with an ophthalmologist.

By writing a PBS prescription for the treatment of glaucoma, the prescriber is certifying the criteria set out in these guidelines are satisfied, and use of the drug is in accordance with the registered indications – refer to the current Product Information for details.

Note that all anti-glaucoma drugs listed on the PBS for prescribing by authorised optometrists must be delivered in a shared care model.

**Initial Referral to Ophthalmologist**

An authorised optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis and the development of a management plan.

Where clinically important delays are expected before the patient’s first review by an ophthalmologist, the optometrist should seek interim advice on the patient’s management from the ophthalmologist by telephone (or alternate means).

The patient’s consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient’s nominated general practitioner.

Patients being considered for anti-glaucoma therapy with a beta blocking agent should be assessed for any potential cardiovascular or respiratory risk by a medical practitioner (often the patient’s general practitioner), prior to initiating therapy. This assessment should be repeated if a change in dose of the beta blocker is proposed.

Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs under the PBS providing that:

- Periodic review demonstrates the treatment to be effective, and
- Changes to management are only initiated following consultation between treating practitioners.

**Patient Management Plan**

The management plan must be in writing and specify the following:

1. All the agreed components of treatment including any drug therapy;
2. Target pressures and action to be taken if these are not achieved within a specified time frame;
3. An agreed approach to monitoring visual fields and optic disc imaging and action to be taken following changes in visual fields;
4. Triggers for referral for more immediate ophthalmological and general practitioner review;
5. Likely side effects from agreed treatment and the action to be taken to address these;
6. An agreed schedule for patient review by both practitioners;
7. Who is responsible for performing each of the required tests and the required frequency for performing them;
8. An agreed method for timely communication of clinical findings and patient management between the two practitioners and the patient’s nominated general practitioner.

Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.

The involvement of a pharmacist to provide medicines information, advice relating to administration and techniques to limit systemic absorption and side effects of ophthalmic medications is recommended.
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Section 2 – READY-PREPARED PHARMACEUTICAL BENEFITS

SYMBOLS USED IN THE SCHEDULE
An asterisk ( * ) against the dispensed price of a benefit indicates that the manufacturer’s pack does not coincide with the maximum quantity.

A double dagger ( ‡ ) in the maximum quantity column indicates an item for which the maximum quantity has been specially determined to correspond to the manufacturer’s pack and the manufacturer’s standard pack should be prescribed and supplied. For any item where a maximum quantity greater than 1 is marked with a double dagger ( ‡ ), that maximum quantity should be prescribed and supplied.

A gauge sign ( # ) against the dispensed price of a benefit indicates that the product is not preconstituted and that an extemporaneously-prepared dispensing fee is included in the dispensed price and, where appropriate, an amount for purified water.

Where a STATE is indicated after a manufacturer’s code, that brand may be available only in the State indicated. NSW–(N); Vic–(V); Qld–(Q); SA–(S); WA–(W); Tas–(T).

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

A straight line is drawn between entries for different forms and strengths of an item to indicate clearly the different restrictions which apply to these various forms and strengths.

The maximum quantity and/or number of repeats in respect of an item shown in the Schedule may be varied by the Chief Executive Medicare when approving an Authority Prescription or an Authority to Prescribe. The quantity and number of repeats shown on the authority shall be supplied. (See Explanatory Notes). Payment will be made on the basis of the price shown for that item in the Schedule.

BRAND EQUIVALENCE
‘a’ located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

For other brands of an item, i.e., those not indicated as above, it is unknown whether or not they are equivalent. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.

‘b’ attached to brand names indicates that these brands are also equivalent, but that it is not known if there is equivalence between brands marked ‘a’ and brands marked ‘b’.

BRAND PREMIUM POLICY
The Brand Premium Policy was introduced on 1 December 1990 to increase price competition by allowing pharmaceutical manufacturers to set their own price on multi-branded items listed on the Pharmaceutical Benefits Scheme and to encourage the development of the generic pharmaceutical industry in Australia. The policy does this by increasing prescribers’ and patients’ consciousness about the price of drugs. In effect, it makes both groups question whether it is necessary for the patient to pay more for the drugs when a cheaper brand is available. The policy also allows companies to establish prices taking into account competition and consumer acceptance.

The policy operates where there is more than one brand of a particular drug available through the Pharmaceutical Benefits Scheme and where the brands are therapeutically interchangeable. Due to this, the policy mainly applies to out of patent drugs.

Basically the policy operates by:

- the Australian Government subsidising a drug to the level of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium);
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier(s) of the lowest priced brand(s); and
- the patient paying the brand premium which is the price difference between the lowest price brand and the brand prescribed.

If a prescription is written generically or for the lowest priced brand, and the lowest priced brand is supplied, there is no brand premium payable.

‘B’ located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item.
If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by ‘T’ and ‘B’ respectively.

If a brand of a drug which is subject to a special patient contribution also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by ‘S’ and ‘B’ respectively.

**THERAPEUTIC GROUP PREMIUM POLICY**

The Therapeutic Group Premium Policy was introduced on 1 February 1998 as an extension of the Brand Premium Policy to encourage greater competition between manufacturers of drugs and to make doctors and patients more aware of the costs of medicines.

The Therapeutic Group Premium policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety, efficacy and health outcomes.

Basically the policy operates by:

- the Australian Government subsidising drugs within a defined therapeutic sub-group to the level of the lowest priced drug in the sub-group;
- suppliers of other drugs within that sub-group being able to set prices above the price charged by the supplier(s) of the lowest priced drug; and
- the patient paying the therapeutic group premium which is the price difference between the lowest price drug and the drug prescribed.

‘T’ located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item.

If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by ‘T’ and ‘B’ respectively.

The success of the Government in controlling prices of products supplied through the Pharmaceutical Benefits Scheme has often been criticised by the pharmaceutical industry. Under both the Brand Premium Policy and the Therapeutic Group Premium Policy, suppliers of multi-branded items and therapeutically similar drugs are able to set their own prices at a level that they think the market will bear. At the same time, the prescriber and the patient can decide whether it is necessary to pay more for a particular brand or drug when a cheaper one is available and is therapeutically interchangeable.

The brand premium or therapeutic group premium does not count toward the patient’s safety net.

It should be noted that the brand premium or therapeutic group premium is not a Government charge or revenue. The premium arises from the manufacturer’s price and the majority goes to the manufacturer with wholesalers and pharmacists receiving a small percentage.
Prescriber Bag
<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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</table>
| 3451P  | ADRENALINE
Adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules                                                   | 1                | 20.68                         | Link Medical Products Pty Ltd |
| 3453R  | ATROPINE
ATROPINE Injection 600 micrograms in 1 mL, 10                                                                 | 1                | 20.88                         | Pfizer Australia Pty Ltd    |
| 10016E | BENZTROPINE
benztpine mesylate 2 mg/2 mL injection, 10 x 2 mL vials                                                        | 1                | 287.65                        | Benztpine Omega             |
| or     |                                                                                                                     |                  |                               |                             |
| 3457Y  | BENZTROPINE
benztpine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules                                                     | 1                | 103.93                        | Cogentin                    |
| or     |                                                                                                                     |                  |                               |                             |
| 3486L  | BENZYPENICILLIN
benztpenicillin 600 mg injection, 1 x 600 mg vial                                                              | 5                | *31.96                        | BenPen                      |
| or     |                                                                                                                     |                  |                               |                             |
| 3485K  | PROCAINE PENICILLIN
procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes                                                 | 1                | 92.56                         | Cilicaine                   |
| or     |                                                                                                                     |                  |                               |                             |
| 3487M  | BENZYPENICILLIN
benztpenicillin 3 g injection, 1 x 3 g vial                                                                       | 1                | 15.44                         | BenPen                      |
| or     |                                                                                                                     |                  |                               |                             |
| 3478C  | CLONAZEPAM
clonazepam 2.5 mg/mL oral liquid, 10 mL                                                                         | ¥1               | 11.07                         | Rivotril                    |
| or     |                                                                                                                     |                  |                               |                             |
| 3470P  | HYDROCORTISONE SODIUM Succinate
hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 2                | *18.04                        | Solu-Cortef                 |
| or     |                                                                                                                     |                  |                               |                             |
| 3471Q  | HYDROCORTISONE SODIUM Succinate
hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 1                | 16.83                         | Solu-Cortef                 |
| or     |                                                                                                                     |                  |                               |                             |
| 3458B  | DIAZEPAM
diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules                                                          | 1                | 13.68                         | Hospira Pty Limited         |
| or     |                                                                                                                     |                  |                               |                             |
| 10244E | DIPHTHERIA TOXOID + TETANUS TOXOID
diphtheria toxoid 2 Li/0.5 mL + tetanus toxoid 2 Li/0.5 mL injection, 10 x 0.5 mL vials | 1                | 144.59                        | MassBiologics tetanus and diphtheria toxoids adsorbed |
| or     |                                                                                                                     |                  |                               |                             |
| 3463G  | DIPHTHERIA TOXOID + TETANUS TOXOID
diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes | 2                | *144.60                       | ADT Booster                 |
| or     |                                                                                                                     |                  |                               |                             |
| 3466K  | FRUSEMIDE
frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules                                                               | 1                | 8.63                          | Lasix                       |
| or     |                                                                                                                     |                  |                               |                             |
| 3467L  | GLUCAGON HYDROCHLORIDE
glucagcon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1                | 50.55                         | GlucaGen Hypokit            |
| or     |                                                                                                                     |                  |                               |                             |
| 3475X  | GLYCERYL TRINITRATE
glyceryl trinitrate 400 microgram/actuation spray, 200 actuations                               | ¥1               | 20.47                         | Nitrolingual Pumpspray      |
| or     |                                                                                                                     |                  |                               |                             |
| 3456X  | HALOPERIDOL
haloperidol 5 mg/mL injection, 10 x 1 mL ampoules                                                              | 1                | 22.62                         | Serenace                    |
<p>| or     |                                                                                                                     |                  |                               |                             |</p>
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<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<td>CHLORPROMAZINE chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules</td>
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<td>HYOSCINE BUTYLBROMIDE hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
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<td>LIGNOCaine lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules</td>
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<td>37.67</td>
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<td>METHOXYFLURANE methoxyflurane 999.9 mg/g inhalation: solution, 1 x 3 mL bottle</td>
<td>1</td>
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<td>Penthrox DV</td>
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<td>METOCLOPRAMIDE metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules or</td>
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<td>PROCHLORPERAZINE prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules</td>
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<td>17.89</td>
<td>Stemetil SW</td>
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<td>10178Q</td>
<td>MIDAZOLAM midazolam 5 mg/mL injection, 10 x 1 mL ampoules</td>
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<td>Pfizer Australia Pty Ltd PF</td>
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<td>3479D</td>
<td>MORPHEME morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules or</td>
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<td>3480E</td>
<td>MORPHEME morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules</td>
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<td>2200T</td>
<td>NALOXONE naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
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<td>*203.56</td>
<td>Naloxone minijet UC</td>
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<td>10251M</td>
<td>OXYTOCIN oxytocin 10 international units/mL injection, 5 x 1 mL ampoules</td>
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<td>Oxytocin Sandoz SZ</td>
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<td>10213M</td>
<td>PHYTOMENADIONE phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules</td>
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<td>3488N</td>
<td>PROMETHAZINE promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules</td>
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<td>Salbutamol-2.5 QA</td>
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<td>Salbutamol 2.5 SA</td>
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<td>or</td>
<td>or</td>
<td>¶1</td>
<td>11.36</td>
<td>Pharmacor Salbutamol 2.5 CR</td>
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<tr>
<td>or</td>
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<td>¶1</td>
<td>11.96</td>
<td>Salbutamol Actavis UA</td>
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<tr>
<td>or</td>
<td>or</td>
<td>¶1</td>
<td>11.36</td>
<td>Ventolin Nebules GK</td>
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</table>

Note: * denotes a higher price than usual.
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<th>Max. Qty</th>
<th>Qty</th>
<th>Price for Max. Qty</th>
<th>Brand Name and Manufacturers</th>
</tr>
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</table>
| 3497C  | **SALBUTAMOL**  
salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | \(\dagger\) 1 | 11.60 a | $11.60             | Asmol 5 uni-dose AF          |
|        |                                                            |          |     |                   | a Butamol 5 QA               |
|        |                                                            |          |     |                   | a APO-Salbutamol TX          |
|        |                                                            |          |     |                   | a Salbutamol Actavis UA      |
|        |                                                            |          |     |                   | a GenRx Salbutamol GX        |
|        |                                                            |          |     |                   | a Pharmacor Salbutamol 5 CR  |
|        |                                                            |          |     |                   | a Salbutamol Sandoz SZ       |
|        |                                                            |          |     |                   | a Salbutamol-GA GN           |
| 3497C  | **SALBUTAMOL**  
salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | \(\dagger\) 1 | 12.18 a | $12.18             | Ventolin Nebules GK          |
|        |                                                            |          |     |                   | a Tramal 100 CS              |
|        |                                                            |          |     |                   | a Tramadol ACT GN            |
|        |                                                            |          |     |                   | a Tramadol Sandoz SZ         |
General Pharmaceutical Benefits
## ALIMENTARY TRACT AND METABOLISM

### STOMATOLOGICAL PREPARATIONS

#### Antiinfectives and antiseptics for local oral treatment

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Manufacturer</th>
<th>Dose</th>
<th>Form</th>
<th>Administration</th>
<th>Price</th>
<th>Safety Net</th>
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<tbody>
<tr>
<td>2931G</td>
<td>AMPHOTERICIN B Fungilin</td>
<td>10 mg lozenge</td>
<td>20</td>
<td>12.37</td>
<td>13.52</td>
<td></td>
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<tr>
<td>3033P</td>
<td>NYSTATIN Mycostatin</td>
<td>100 000 international units/mL</td>
<td>24 mL</td>
<td>11.48</td>
<td>12.63</td>
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<tr>
<td>3343Y</td>
<td>NYSTATIN Nilstat</td>
<td>100 000 international units/mL</td>
<td>24 mL</td>
<td>11.48</td>
<td>12.63</td>
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Other agents for local oral treatment

#### BENZYDAMINE

<table>
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<th>Code</th>
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<tr>
<td>1121B</td>
<td>benzydamine hydrochloride Difflam</td>
<td>0.15%</td>
<td>500 mL</td>
<td>22.60</td>
<td>23.75</td>
<td></td>
</tr>
<tr>
<td>5032W</td>
<td>benzydamine hydrochloride Difflam</td>
<td>0.15%</td>
<td>500 mL</td>
<td>22.60</td>
<td>23.75</td>
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### DRUGS FOR ACID RELATED DISORDERS

#### ANTACIDS

Combinations and complexes of aluminium, calcium and magnesium compounds

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<th>Administration</th>
<th>Price</th>
<th>Safety Net</th>
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<tbody>
<tr>
<td>2159P</td>
<td>ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + MAGNESIUM TRISILICATE Gastrogel</td>
<td>250 mg/5 mL + 120 mg/5 mL + 120 mg/5 mL</td>
<td>500 mL</td>
<td>18.04</td>
<td>19.19</td>
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ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE

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<th>Form</th>
<th>Administration</th>
<th>Price</th>
<th>Safety Net</th>
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<tr>
<td>2157M</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Mylanta P</td>
<td>200 mg + 200 mg</td>
<td>5 mL</td>
<td>18.04</td>
<td>19.19</td>
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### DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

#### H2-receptor antagonists

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<th>Form</th>
<th>Administration</th>
<th>Price</th>
<th>Safety Net</th>
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<tr>
<td>1158Y</td>
<td>Cimetidine Magicul 400</td>
<td>400 mg tablet</td>
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Famotidine

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<th>Code</th>
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<th>Form</th>
<th>Administration</th>
<th>Price</th>
<th>Safety Net</th>
</tr>
</thead>
<tbody>
<tr>
<td>2487X</td>
<td>Famotidine Pamacid 20</td>
<td>20 mg tablet</td>
<td>60</td>
<td>11.80</td>
<td>12.95</td>
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</table>

Note: Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.
### ALIMENTARY TRACT AND METABOLISM

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<thead>
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<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $ for Max. Qty $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2488Y NP</td>
<td>famotidine 40 mg tablet, 30</td>
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<td>11.80</td>
<td>12.95</td>
<td>a Pepzan GN a Terry White Chemists Famotidine Ausfam 40 QA</td>
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<tr>
<td>1505F NP</td>
<td>nizatidine 150 mg capsule, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>18.77</td>
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<td>a Nizac LN</td>
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<tr>
<td>1504E NP</td>
<td>nizatidine 300 mg capsule, 30</td>
<td>1</td>
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<td>18.77</td>
<td>19.92</td>
<td>a Nizac LN</td>
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<tr>
<td>1978D NP,MW</td>
<td>ranitidine 150 mg tablet, 60</td>
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<td>5</td>
<td>..</td>
<td>12.12</td>
<td>13.27</td>
<td>a APO-Ranitidine TX</td>
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<tr>
<td>1937Y NP</td>
<td>ranitidine 150 mg tablet: effervescent, 30</td>
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<td>5</td>
<td>..</td>
<td>$1.15</td>
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<td>8162N NP</td>
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<td>5</td>
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<td>$24.86</td>
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<td>13.27</td>
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</table>

### NIZATIDINE

**Note**

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

### RANITIDINE

**Note**

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

### Proton pump inhibitors

**ESOMEPRAZOLE**

**Restricted benefit**

Maintenance of healed gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus
### ALIMENTARY TRACT AND METABOLISM

<table>
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<tr>
<th>Code</th>
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<td>26.52</td>
<td>Esomeprazole Apotex TX A</td>
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<tr>
<td>NP</td>
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<td>Esomeprazole GxP AF a</td>
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<tr>
<td>8198L</td>
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<td>13.95</td>
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<td>NP</td>
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<tr>
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<td>5</td>
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<td>13.44</td>
<td>14.59</td>
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<td>NP</td>
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<td>Zoton FasTabs PF a</td>
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</table>

### Restricted benefit

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Note**

No applications for increased maximum quantities will be authorised.

### ESOMEPRAZOLE

**Restricted benefit**

Initial treatment of gastric ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

### ESOMEPRAZOLE

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**

Scleroderma oesophagus

**Note**

Continuing Therapy Only:

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

### ESOMEPRAZOLE

**Restricted benefit**

Healing of gastro-oesophageal reflux disease

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

### LANSOPRAZOLE

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**LANSOPRAZOLE**
### ALIMENTARY TRACT AND METABOLISM

<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium/Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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<td></td>
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<td>a Lanzopran RA</td>
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<td>14.68</td>
<td>20 Probit</td>
<td>Probit TX</td>
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<td>Probit TX</td>
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<td>16.01</td>
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<td>14.68</td>
<td>2.48</td>
<td>16.01</td>
</tr>
</tbody>
</table>

**OMEPRAZOLE**

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Zollinger-Ellison syndrome

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

**PANTOPRAZOLE**

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Zollinger-Ellison syndrome
<table>
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<tr>
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<th>Premium $</th>
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**PANTOPRAZOLE**

**Restricted benefit**
Initial treatment of peptic ulcer

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

**Note**
No applications for increased repeats will be authorised.

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RABEPRAZOLE

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**RABEPRAZOLE**

**Restricted benefit**

Initial treatment of peptic ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

No applications for increased repeats will be authorised.

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ALIMENTARY TRACT AND METABOLISM

## Combinations for eradication of Helicobacter pylori

**ESOMEPRAZOLE (©) CLARITHROMYCIN (©) AMOXYCILLIN**

**Restricted benefit**

Eradication of Helicobacter pylori associated with peptic ulcer disease

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

### ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE

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## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

**Belladonna alkaloids, tertiary amines**

**ATROPINE**

Note

Shared Care Model:

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

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**ATROPINE**

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### PROPULSIVES

**Propulsives**

**DOMPERIDONE**

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### ALIMENTARY TRACT AND METABOLISM

#### ANTIEMETICS AND ANTINAUSEANTS

**Serotonin (5HT3) antagonists**

**Granisetron**

**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

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**Granisetron**

**Authority required (STREAMLINED)**

4102

Nausea and vomiting

Clinical criteria:

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

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**Granisetron**

**Authority required (STREAMLINED)**

4092

Nausea and vomiting

Clinical criteria:

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

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

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**Granisetron**

**Authority required (STREAMLINED)**

4092

Nausea and vomiting

Clinical criteria:

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

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**Ondansetron**

**Authority required (STREAMLINED)**

3611

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

**Note**

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

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</table>
### ONDANSETRON

**Restricted benefit**

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

**Note**

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

**ONDANSETRON**

**Authority required (STREAMLINED)**

**ONDANSETRON**

**Restricted benefit**

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**ONDANSETRON**

**Authority required (STREAMLINED)**

**ONDANSETRON**

**Restricted benefit**

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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**Note**

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

**ONDANSETRON**

**Authority required (STREAMLINED)**

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

### Table: Medications

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**ONDANSETRON**

**Restricted benefit**

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

**PALONOSETRON**

**Restricted benefit**

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

**Note**

No applications for increased maximum quantities will be authorised. Palonosetron is not PBS-subsidised for administration with oral 5-HT3.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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**Other antiemetics**

**APREPITANT**

**Authority required (STREAMLINED)**

4211

Nausea and vomiting

**Clinical criteria:**

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,

AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

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

**Authority required (STREAMLINED)**

4215

Nausea and vomiting

**Clinical criteria:**

The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,

AND

Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

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

**Authority required (STREAMLINED)**

4213

Nausea and vomiting

**Clinical criteria:**

The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle,

AND

Patient must have had a prior episode of chemotherapy induced nausea or vomiting,

AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; carboplatin; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dacarbazine; daunorubicin; doxorubicin; etoposide; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; oxaliplatin; raltitrexed.

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

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

**Note**

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

**Note**
ALIMENTARY TRACT AND METABOLISM

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

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

2518M

NP

aprepitant 165 mg capsule, 1

1 5 .. 138.13 37.70 Emend MK

PROCHLORPERAZINE

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

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

2895J

NP

prochlorperazine maleate 25 mg suppository, 5

‡1 2 .. 20.27 21.42 Stemetil SW

a Pharmacor Prozine CR

a ProCalm QA

a Prochlorperazine AN EA

a Prochlorperazine-GA GN

a Prochlorperazine GH GQ

a Stemzine AV

a Stemetil SW

2369Q

NP

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

1 .. .. 17.89 19.04 Stemetil SW

5208D

DP

prochlorperazine maleate 25 mg suppository, 5

‡1 .. .. 20.27 21.42 Stemetil SW

a APO-Prochlorperazine TX

a Pharmacor Prozine CR

a ProCalm QA

a Prochlorperazine AN EA

a Prochlorperazine-GA GN

a Prochlorperazine GH GQ

a Stemzine AV

a Stemetil SW

5206B

DP

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

‡1 2 .. 2.70 10.89 9.34 a Stemetil SW

a Stemzine AV

a Stemetil SW

3374N

DP

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

2 .. .. *30.58 31.73 Hospira Pty Limited HH

BILE AND LIVER THERAPY

BILE THERAPY

Bile acid preparations

URSODEOXYCHOLIC ACID

Authority required (STREAMLINED)

1700

Primary biliary cirrhosis

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

Note
Continuing Therapy Only:

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

8448P

ursodeoxycholic acid 250 mg capsule, 2 2 .. *317.22 37.70 a Ursofalk OA
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<th>Name, Restriction, Manner of Administration and Form</th>
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**DRUGS FOR CONSTIPATION**

**Contact laxatives**

**BISACODYL**

**Restricted benefit**
- Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
- Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities
- For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
- Patients receiving palliative care
- Terminal malignant neoplasia
- Anorectal congenital abnormalities

**Restricted benefit**
- Megacolon

**Bulk-forming laxatives**

**RHAMNUS FRANGULA + STERCULIA**

**Restricted benefit**
- Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
- Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities
- For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult
- Patients receiving palliative care
- Terminal malignant neoplasia
- Anorectal congenital abnormalities

**Restricted benefit**
- Megacolon

**Osmotically acting laxatives**

**LACTULOSE**

**Restricted benefit**
- Hepatic coma or precoma (chronic porto-systemic encephalopathy)
- Constipation in patients with malignant neoplasia

**3064G**

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<th>Code</th>
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<td>10.70</td>
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**a** Urosan BZ
MACROGOL-3350

**Restricted benefit**

Constipation

**Clinical criteria:**

Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

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

AND

The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

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

**Note**

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

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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>19.72 $</td>
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MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE

**Restricted benefit**

Constipation

**Clinical criteria:**

Patient must have malignant neoplasia.

**Restricted benefit**

Constipation

**Clinical criteria:**

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

AND

The condition must be unresponsive to other oral therapies.

**Restricted benefit**

Chronic constipation

**Clinical criteria:**

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

**Restricted benefit**

Faecal impaction

**Clinical criteria:**

The condition must be inadequately controlled with first line interventions such as bulk-forming agents.
| Code   | Name, Restriction, Manner of Administration and Form                                                                 | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | Manufacturer |
|--------|------------------------------------------------------------------------------------------------------------------------|-------------------|-------------|-----------|-------------------------------|------------------------------------------|--------------------------------|
| 8612G  | macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets | 1                 | 5           |          | 18.57                         | 19.72                                    | APO-MACROGOL plus ELECTROLYTES | TX          |
|        |                                                                                                                        |                   |             |           |                               |                                          | LaxaCon                           | GN          |
|        |                                                                                                                        |                   |             |           |                               |                                          | lax-sachets                         | AE          |
|        |                                                                                                                        |                   |             |           |                               |                                          | Macrovia                           | QA          |
|        |                                                                                                                        |                   |             |           |                               |                                          | Molaxole                           | HM          |
|        |                                                                                                                        |                   |             |           |                               |                                          | Movicol                            | NE          |
| 10126Y | macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL | 2                 | 5           |          | 22.52                         | 23.67                                    | Movicol Liquid                         | NE          |
| 1263L  | bisacodyl 10 mg/5 mL enema, 25 x 5 mL                                                                                   | 1                 | 2           |          | 38.28                         | 37.70                                    | Bisalax                            | AS          |
|        |                                                                                                                        |                   |             |           |                               |                                          | Micolette                           | AE          |
|        |                                                                                                                        |                   |             |           |                               |                                          | Microfax                           | JT          |

**Enemas**

**BISACODYL**

**Restricted benefit**

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

**Restricted benefit**

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

**Restricted benefit**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

**Restricted benefit**

Patients receiving palliative care

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megaconol

**SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

**Restricted benefit**

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

**Restricted benefit**

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

**Restricted benefit**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

**Restricted benefit**

Patients receiving palliative care

**Restricted benefit**

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megaconol

**GLYCEROL**

**Restricted benefit**

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function
ALIMENTARY TRACT AND METABOLISM

**Code**
**Name, Restriction, Manner of Administration and Form**
Max. Qty (Packs)
No. of Rpts
Premium $ for Max. Qty $
Maximum Recordable Value for Safety Net $
Brand Name and Manufacturer

**Restricted benefit**
Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

**Restricted benefit**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

**Restricted benefit**
Patients receiving palliative care

**Restricted benefit**
Terminal malignant neoplasia

**Restricted benefit**
Anorectal congenital abnormalities

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### ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

#### INTESTINAL ANTIINFECTIVES

##### Antibiotics

**NYSTATIN**
nystatin 500,000 international units
capsule, 50

**1699K**
nystatin 500,000 international units
capsule, 50

**3345C**
nystatin 500,000 international units
tablet, 50

**1696G**
nystatin 500,000 international units
tablet, 50

**3342X**
nystatin 500,000 international units
tablet, 50

**RIFAXIMIN**
**Authority required**
Prevention of hepatic encephalopathy

**Clinical criteria:**
The treatment must be in combination with lactulose, if lactulose is tolerated,

**AND**
Patient must have had prior episodes of hepatic encephalopathy.

**Treatment criteria:**
Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

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

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

**VANCOMYCIN**
**Authority required**
Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole

**Authority required**
Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole

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

**3113W**
vancomycin 125 mg capsule, 20

**3114X**
vancomycin 250 mg capsule, 20
ALIMENTARY TRACT AND METABOLISM

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRATE

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

†1.. .. 13.25 14.40 a O.R.S. AS

3196F np sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets

ANTIPROPULSIVES

Antipropulsives

DIPHENOXYLATE + ATROPINE SULFATE

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

‡1.73 10.54 9.96 a Lomotil IV

2501P np diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20

LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 12

§0.75 9.22 9.62 a Gastro-Stop Loperamide AS

1571Q np loperamide hydrochloride 2 mg capsule, 12

INTESTINAL ANTIINFLAMMATORY AGENTS

Corticosteroids acting locally

BUDESONIDE

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

†1.. .. 211.65 37.70 Budenofalk OA

10034D np budesonide 2mg/application enema, 2 x 14 applications

HYDROCORTISONE ACETATE

Restricted benefit

Proctis

Restricted benefit

Ulcerative colitis

Note
Continuing Therapy Only:
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§*40.78 37.70 Colifoam HM

1502C np hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g

PREDNISOLONE SODIUM PHOSPHATE

Note
Continuing Therapy Only:
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†211.68 37.70 Predsol QA

1920C np prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL

PREDNISOLONE SODIUM PHOSPHATE

Restricted benefit
<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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<tr>
<td>2554K</td>
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<td>Predsol QA</td>
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**Aminosalicylic acid and similar agents**

**BALSALAZIDE**

**Authority required (STREAMLINED)**

1708 Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

1709 Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Continuing Therapy Only:

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8845M balsalazide sodium 750 mg capsule, 180 1 5 .. 125.19 37.70 Colazide PK

**MESALAZINE**

**Authority required (STREAMLINED)**

1708 Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

1709 Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Continuing Therapy Only:

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

8599N mesalazine 1 g granules: modified release, 100 x 1 g sachets

9353G mesalazine 1.2 g tablet: modified release, 60 tablets

9206M mesalazine 1.5 g granules, 60 x 1.5 g sachets

8598M mesalazine 500 mg granules, 100 x 500 mg sachets

**MESALAZINE**

**Authority required (STREAMLINED)**

1708 Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

1709 Ulcerative colitis where intolerance to sulfasalazine exists

**Authority required (STREAMLINED)**

2268 Crohn disease where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

2269
### ALIMENTARY TRACT AND METABOLISM

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**Note**

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**Note**

Continuing Therapy Only:

**Note**

Not for the treatment of Crohn disease.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

**Note**

Not for the treatment of Crohn disease.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

**Note**

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.
<table>
<thead>
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<td>a Salazopyrin-EN PF</td>
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**Note**
Not for the treatment of Crohn disease

**Note**
Continuing Therapy Only:
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8021E</td>
<td>pancreatic extract 25 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*148.08</td>
<td>37.70</td>
<td>Creon 25,000</td>
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<tr>
<td>9412J</td>
<td>pancreatic extract 40 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*230.30</td>
<td>37.70</td>
<td>Creon 40,000</td>
</tr>
<tr>
<td>5453B</td>
<td>pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g</td>
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<td>10</td>
<td>..</td>
<td>*142.12</td>
<td>37.70</td>
<td>Creon Micro</td>
</tr>
</tbody>
</table>

**PANCREATIC EXTRACT**

**Restricted benefit**
For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>9226N</td>
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<td>21</td>
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<td>Creon 10,000</td>
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<tr>
<td>9227P</td>
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<td>Creon 25,000</td>
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<td>9413K</td>
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<td>*230.30</td>
<td>37.70</td>
<td>Creon 40,000</td>
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<td>pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g</td>
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<td>21</td>
<td>..</td>
<td>*142.12</td>
<td>37.70</td>
<td>Creon Micro</td>
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</table>

**PANCRELIPASE**

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<th>Brand Name and Manufacturer</th>
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<td>8366H</td>
<td>pancrépase 25 000 units capsule, 100</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*138.24</td>
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<td>Panzytrat 25000</td>
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</tbody>
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**PANCRELIPASE**

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<td>9229R</td>
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<td>21</td>
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<td>Panzytrat 25000</td>
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**DRUGS USED IN DIABETES**

**INSULINS AND ANALOGUES**

*Insulins and analogues for injection, fast-acting*

**INSULIN ASPART**

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
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<td>NovoRapid</td>
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<td>8435Y</td>
<td>insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
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**INSULIN GLULISINE**

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<td>*159.61</td>
<td>37.70</td>
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**INSULIN LISPRO**

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<th>Brand Name and Manufacturer</th>
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<td>No. of Rpts</td>
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<td>37.70</td>
<td>Humalog</td>
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<td>Humalog KwikPen</td>
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<td>Actrapid</td>
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**Insulins and analogues for injection, intermediate-acting**

**INSULIN ISOPHANE BOVINE**

*Authority required*

Diabetes mellitus

**Clinical criteria:**

Patient must be intolerant to human insulin.

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

**INSULIN ASPART + INSULIN ASPART PROTAMINE**

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<td>37.70</td>
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**INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN**

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**INSULIN NEUTRAL BOVINE**

*Authority required*

Diabetes mellitus

**Clinical criteria:**

Patient must be intolerant to human insulin.

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### ALIMENTARY TRACT AND METABOLISM

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**Insulins and analogues for injection, long-acting**

**INSULIN DETEMIR**

**Restricted benefit**

Type 1 diabetes

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**BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS**

**Biguanides**

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**Sulfonamides, urea derivatives**

**GLIBENCLAMIDE**

**Caution**

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

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**GLICLAZIDE**

**Caution**

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

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**GLIMEPIRIDE**

**Caution**

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

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<th>Maximum Recordable Value for Safety Net $</th>
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<td>8.19</td>
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<td>a APO-Glimepiride TX</td>
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## ALIMENTARY TRACT AND METABOLISM

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### GLIPIZIDE

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

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<tr>
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### Combinations of oral blood glucose lowering drugs

**ALOGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

4423
Diabetes mellitus type 2

**Clinical criteria:**

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a...
A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

4427
Diabetes mellitus type 2
Treatment Phase: Continuing

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

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

### LINAGLIPTIN + METFORMIN

**Authority required (STREAMLINED)**

4423
Diabetes mellitus type 2

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

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

**Authority required (STREAMLINED)**

4448
Diabetes mellitus type 2
Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

**Note**
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<td>10044P</td>
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<td>Trajentamet BY</td>
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**METFORMIN + GLIBENCLAMIDE**

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

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<td>8810Q</td>
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<td>17.02</td>
<td>18.17</td>
<td>Glucovance AL</td>
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**ROSIGLITAZONE + METFORMIN**

**Authority required**
Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have a contraindication to a sulfonylurea; OR
- Patient must not have tolerated a sulfonylurea,

**AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin;
- OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

**Note**
This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

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<tr>
<td>9059T</td>
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<td>Avandamet GK</td>
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<tr>
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<td>Avandamet GK</td>
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</tbody>
</table>

**SAXAGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.
4423
Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

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

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

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

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

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

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

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

Authority required (STREAMLINED)

4451
Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Note

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

10048W

saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56

1 5 .. 62.77 37.70 Kombiglyze XR 2.5/1000 AP

10051B

saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28

1 5 .. 61.05 37.70 Kombiglyze XR 5/1000 AP

10055F

saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28

1 5 .. 60.12 37.70 Kombiglyze XR 5/500 AP

SITAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423
Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

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

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

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.
Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

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

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

**Authority required (STREAMLINED)**

4309
Diabetes mellitus type 2
Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

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

<table>
<thead>
<tr>
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<td>Janumet XR</td>
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<td>5</td>
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<td>61.05</td>
<td>37.70</td>
<td>Janumet</td>
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</table>

**VILDAGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

4423
Diabetes mellitus type 2

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records.
A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Authority required (STREAMLINED)**

4308

Diabetes mellitus type 2

Treatment Phase: Continuing

**Clinical criteria:**

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

**Note**

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

<table>
<thead>
<tr>
<th>Code</th>
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<td>Galvumet 50/1000</td>
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<td>5</td>
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<td>37.70</td>
<td>Galvumet 50/500</td>
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<td>37.70</td>
<td>Galvumet 50/850</td>
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</table>

**Alpha glucosidase inhibitors**

**ACARBOSE**

NP

acarbose 100 mg tablet, 90

1 | 5 | .. | 45.87 | 37.70 | Glucobay 100 | BN |

NP

acarbose 50 mg tablet, 90

1 | 5 | .. | 34.87 | 36.02 | Glucobay 50 | BN |

**Thiazolidinediones**

**PIOGLITAZONE**

**Authority required (STREAMLINED)**

4363

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea,

**AND**

- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea,

**AND**

- Patient must have, or have had, an HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

**Authority required (STREAMLINED)**

4388
Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with insulin,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

**Authority required (STREAMLINED)**

4364
Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**ROSIGLITAZONE**

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

**AND**

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
Patient must not have tolerated a combination of metformin and a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Note
This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

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Dipeptidyl peptidase 4 (DPP-4) inhibitors

ALOGLIPTIN
Authority required (STREAMLINED)

4349
Diabetes mellitus type 2

Clinical criteria:
The treatment must be in combination with metformin; OR
The treatment must be in combination with a sulfonylurea.

AND

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this
Note

Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitzone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

LINAGLIPTIN

Authority required (STREAMLINED)

4488
Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

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

Note

Linagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitzone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

SAXAGLIPTIN

Authority required (STREAMLINED)

4520
Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

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

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

Note
Saxagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

SITAGLIPTIN
Authority required (STREAMLINED)
4519
Diabetes mellitus type 2
Clinical criteria:
The treatment must be in combination with metformin; OR
The treatment must be in combination with a sulfonylurea,
AND
Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.
The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

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

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

Note
Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.
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**VILDAGLIPTIN**  
*Authority required (STREAMLINED)*  
4467  
Diabetes mellitus type 2  

**Clinical criteria:**  
The treatment must be in combination with metformin; OR  
The treatment must be in combination with a sulfonylurea,  

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:  
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.  

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records.  
A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with vildagliptin.  

**Note**  
Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.  

3415R  
vildagliptin 50 mg tablet, 60  

**Other blood glucose lowering drugs, excl. insulins**  

**CANAGLIFLOZIN**  
*Authority required*  
Diabetes mellitus type 2  

**Clinical criteria:**  
The treatment must be in combination with metformin; OR  
The treatment must be in combination with a sulfonylurea,  

**AND**  
The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,  

**AND**  
Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR  
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.  

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
**ALIMENTARY TRACT AND METABOLISM**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2873F</td>
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<td>37.70</td>
<td>Invokana JC</td>
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<tr>
<td>2987F</td>
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<td>5</td>
<td>..</td>
<td>96.61</td>
<td>37.70</td>
<td>Invokana JC</td>
</tr>
</tbody>
</table>

**DAPAGLIFLOZIN**  
**Authority required (STREAMLINED)**

**4844**  
Diabetes mellitus type 2

**Clinical criteria:**  
The treatment must be in combination with metformin; OR  
The treatment must be in combination with a sulfonylurea,  
AND  
Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR  
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:  
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  
(b) Had red cell transfusion within the previous 3 months.

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

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

**Authority required (STREAMLINED)**

**4825**  
Diabetes mellitus type 2

**Clinical criteria:**  
The treatment must be in combination with insulin,  
AND  
Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR  
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with
insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

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

**Note**

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

**Note**

Dapagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

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**Table:**

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>10011X</td>
<td>dapagliflozin 10 mg tablet. 28</td>
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<td>..</td>
<td>58.66</td>
<td>37.70</td>
<td>Forxiga AP</td>
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**EMPAGLIFLOZIN**

**Authority required (STREAMLINED)**

484B

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.

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

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

**Note**
### ALIMENTARY TRACT AND METABOLISM

<table>
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<th>Code</th>
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<td>62.37</td>
<td>37.70</td>
<td>emagliflozin 10 mg tablet, 30</td>
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<td>5</td>
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<tr>
<td>10202Y</td>
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<td>5</td>
<td></td>
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<td>37.70</td>
<td>emagliflozin 25 mg tablet, 30</td>
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<td>5</td>
<td>62.37</td>
<td>37.70</td>
<td></td>
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### EXENATIDE

**Authority required (STREAMLINED)**

4856

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, AND
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

**Authority required (STREAMLINED)**

4857

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, AND
- The treatment must be in combination with a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.
The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

**Note**

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>exenatide 5 microgram/0.02 mL injection, 60 unit doses</td>
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<td>5</td>
<td>..</td>
<td>70.34</td>
<td>37.70</td>
<td>Byetta 5 microgram AP</td>
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</table>

**VITAMINS**

**VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO**

**Vitamin D and analogues**

**CALCITRIOL**

**Authority required (STREAMLINED)**

1165 Hypocalcaemia due to renal disease

**Authority required (STREAMLINED)**

1166 Hypoparathyroidism

**Authority required (STREAMLINED)**

1167 Hypophosphataemic rickets

**Authority required (STREAMLINED)**

1467 Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

2636 Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

<table>
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<td>30.62</td>
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**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12**

**Vitamin B1, plain**

**THIAMINE**

**Authority required (STREAMLINED)**

2384
### MINERAL SUPPLEMENTS

#### CALCIUM

**Calcium**

**CALCIUM Authority required (STREAMLINED)**

4586

Hyperphosphataemia

**Clinical criteria:**

The condition must be associated with chronic renal failure.

<table>
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<tr>
<th>Code</th>
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<td>Cal-500 PP</td>
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<td>3117C</td>
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<td>22.54</td>
<td>23.69</td>
<td>Calci-Tab 600 AE</td>
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#### POTASSIUM

**Potassium**

**POTASSIUM CHLORIDE**

**Note**

For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
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<tr>
<td>2642C</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets</td>
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<td>1</td>
<td>..</td>
<td>*13.22</td>
<td>14.37</td>
<td>Duro-K NM</td>
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<tr>
<td>1841X</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 200 tablets</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>*2.94</td>
<td>16.16</td>
<td>Slow-K NV</td>
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**POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**

<table>
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<tr>
<th>Code</th>
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<tr>
<td>3012M</td>
<td>potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) tablet: effervescent, 60</td>
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<td>15.48</td>
<td>16.63</td>
<td>Chlorvescent AS</td>
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#### OTHER MINERAL SUPPLEMENTS

**Magnesium**

**MAGNESIUM ASPARTATE DIHYDRATE**

**Authority required**

Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person

**Authority required**

Chronic renal disease in an Aboriginal or a Torres Strait Islander person

<table>
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<tr>
<td>5146W</td>
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<td>1</td>
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<td>14.04</td>
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<td>MagMin (PBS) BB</td>
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#### ANABOLIC AGENTS FOR SYSTEMIC USE

### ANABOLIC STEROIDS

**Estren derivatives**

**NANDROLONE DECANOATE**

**Authority required**

Monotherapy for osteoporosis, where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

**Authority required**

Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment
**ALIMENTARY TRACT AND METABOLISM**

<table>
<thead>
<tr>
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</tbody>
</table>

**Authority required**
Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval.

**Authority required**
Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004.

**Authority required**
Patients on long-term treatment with corticosteroids.

**Note**
Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

1671Y nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe
Max. Qty 1
No. of Rpts 7
Premium $ 21.54
Dispensed Price for Max. Qty $ 22.69
Brand Name and Manufacturer Deca-Durabolin

**OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**

**Amino acids and derivatives**

**BETAINE**

**Authority required**
Homocystinuria

Clinical criteria:
The treatment must be as adjunctive therapy to current standard care,

AND

The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

10119N betaine 1 g/g oral liquid: powder for, 1 g
Max. Qty 1
No. of Rpts 5
Premium $ 570.55
Dispensed Price for Max. Qty $ 37.70
Brand Name and Manufacturer Cystadane

**Various alimentary tract and metabolism products**

**SAPROPTERIN**

**Authority required**
Hyperphenylalaninaemia

Treatment Phase: Initial

Clinical criteria:
Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

Note
Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

If a 30% or greater reduction in blood phenylalanine levels is not achieved within one month, the patient is no longer eligible for PBS-subsidised treatment with sapropterin.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

10086W sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets
Max. Qty 6
No. of Rpts ..
Premium $ 5306.74
Dispensed Price for Max. Qty $ 37.70
Brand Name and Manufacturer Kuvan
SAPROPTERIN

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency,

AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

**Note**

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## BLOOD AND BLOOD FORMING ORGANS

### ANTIITHROMBOTIC AGENTS

#### Vitamin K antagonists

**WARFARIN**

**Caution**
The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

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#### Heparin group

**DALTEPARIN SODIUM**

**Restricted benefit**
Management of symptomatic venous thromboembolism in a patient with a solid tumour(s)

**Note**
No applications for increased maximum quantities will be authorised.

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**DALTEPARIN SODIUM**

**Restricted benefit**
Haemodialysis

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Platelet aggregation inhibitors excl. heparin

**ABCIXIMAB**

*Authority required (STREAMLINED)*

**1716**

Patients undergoing percutaneous coronary balloon angioplasty

*Authority required (STREAMLINED)*

**1717**

Patients undergoing percutaneous coronary atherectomy

*Authority required (STREAMLINED)*

**1718**
<table>
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<td>Patients undergoing percutaneous coronary stent placement abciximab 10 mg/5 mL injection, 1 x 5 mL vial</td>
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**CLOPIDOGREL**

**Authority required (STREAMLINED)**

4166

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

The treatment must be in combination with aspirin.

**Authority required (STREAMLINED)**

4165

Cardiac stent insertion

**Clinical criteria:**

The treatment must be in combination with aspirin,

AND

The treatment must follow insertion of a cardiac stent.

**Note**

Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note**

Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

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**CLOPIDOGREL**

**Authority required (STREAMLINED)**

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)**

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)**

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

**Authority required (STREAMLINED)**

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of
BLOOD AND BLOOD FORMING ORGANS

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**Authority required (STREAMLINED)**

1721
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)**

1722
Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Note**
Not for prophylaxis of DVT or peripheral arterial disease.

**Note**
Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note**
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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**CLOPIDOGREL + ASPIRIN**

**Authority required (STREAMLINED)**

3880

Treatment of acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

3219

Treatment following cardiac stent insertion

**Authority required (STREAMLINED)**

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Note**

Not for prophylaxis of DVT or peripheral arterial disease.

**Note**

Shared Care Model:

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

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**DIPYRIDAMOLE**

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Note**

Shared Care Model:

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

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**Note**

Shared Care Model:

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

**DIPYRIDAMOLE + ASPIRIN**

Patients undergoing non-urgent percutaneous intervention with intracoronary stenting

**EPTIFIBATIDE**

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes

**PRASUGREL**

Patients with non-Q-wave myocardial infarction

**TICAGRELOR**

Patients with non-Q-wave myocardial infarction

**TIROFIBAN**

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours

**Authority required (STREAMLINED)**

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours

**Authority required (STREAMLINED)**

Patients with non-Q-wave myocardial infarction
Enzymes

RETEPLASE
Restricted benefit
Treatment of acute myocardial infarction within 6 hours of onset of attack

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

RETIEPLASE
Restricted benefit
Treatment of acute myocardial infarction within 12 hours of onset of attack

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

Direct thrombin inhibitors

BIVALIRUDIN
Authority required (STREAMLINED)
3075
A patient undergoing percutaneous coronary intervention

DABIGATRAN
Authority required (STREAMLINED)
4269
Prevention of stroke or systemic embolism

Clinical criteria:
Patient must have non-valvular atrial fibrillation,
AND
Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systematic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

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

Note
No increase in the maximum quantity or number of units may be authorised.
### BLOOD AND BLOOD FORMING ORGANS

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**DABIGATRAN**

**Authority required (STREAMLINED)**

4402

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 30 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Note**

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

**Note**

Shared Care Model:

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

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**DABIGATRAN**

**Authority required (STREAMLINED)**

4369

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 20 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Note**

Shared Care Model:

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

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**DABIGATRAN**

**Authority required (STREAMLINED)**

4381

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 10 days of therapy.

**Treatment criteria:**

Patient must be undergoing total knee replacement.
### Direct factor Xa inhibitors

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**APIXABAN**

**Authority required (STREAMLINED)**

#### 4381
Prevention of venous thromboembolism

**Clinical criteria:**
Patient must require up to 10 days of therapy.

**Treatment criteria:**
Patient must be undergoing total knee replacement.

#### 4359
Prevention of venous thromboembolism

**Clinical criteria:**
Patient must require up to 10 days supply to complete a course of treatment.

**Treatment criteria:**
Patient must be undergoing total hip replacement.

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

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

**Note**

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

#### 5500L NP
apixaban 2.5 mg tablet, 20

**Authority required (STREAMLINED)**

#### 4382
Prevention of venous thromboembolism

**Clinical criteria:**
Patient must require up to 15 days of therapy.

**Treatment criteria:**
Patient must be undergoing total knee replacement.

#### 4409
Prevention of venous thromboembolism

**Clinical criteria:**
Patient must require up to 15 days supply to complete a course of treatment.

**Treatment criteria:**
Patient must be undergoing total hip replacement.

**Note**
No increase in the maximum quantity or number of units may be authorised.
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<td>Eliquis</td>
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</table>

**APIXABAN**

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

Patient must have non-valvular atrial fibrillation,

**AND**

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note**

Shared Care Model:

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

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**2744K**  

NP

apixaban 2.5 mg tablet, 60  

1 5 ..  

101.54 37.70 Eliquis BQ

**2735Y**  

NP

apixaban 5 mg tablet, 60  

1 5 ..  

101.53 37.70 Eliquis BQ

**APIXABAN**

**Authority required (STREAMLINED)**

**4402**

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 30 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Note**

Shared Care Model:

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

**Note**

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

**Note**

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

**Note**

Shared Care Model:

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

**RIVAROXABAN**
### Authority required (STREAMLINED)

**4402**

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 30 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Shared Care Model**

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

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### Authority required (STREAMLINED)

**4369**

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 20 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Shared Care Model**

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

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<td>Xarelto</td>
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### Authority required (STREAMLINED)

**4381**

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 10 days of therapy.

**Treatment criteria:**

Patient must be undergoing total knee replacement.

**Note**

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

**Note**

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

**Shared Care Model**

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

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| RIVAROXABAN  
**Authority required (STREAMLINED)**  
4382  
Prevention of venous thromboembolism  
**Clinical criteria:**  
Patient must require up to 15 days of therapy.  
**Treatment criteria:**  
Patient must be undergoing total knee replacement.  
**Note**  
No increase in the maximum quantity or number of units may be authorised.  
**Note**  
No increase in the maximum number of repeats may be authorised.  
**Note**  
Shared Care Model:  
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.  
9469J rivaroxaban 10 mg tablet, 15 1 .. .. 54.16 37.70 Xarelto BN |
| RIVAROXABAN  
**Authority required (STREAMLINED)**  
4269  
Prevention of stroke or systemic embolism  
**Clinical criteria:**  
Patient must have non-valvular atrial fibrillation,  
**AND**  
Patient must have one or more risk factors for developing stroke or systemic embolism.  
Risk factors for developing stroke or systemic ischaemic embolism are:  
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;  
(ii) age 75 years or older;  
(iii) hypertension;  
(iv) diabetes mellitus;  
(v) heart failure and/or left ventricular ejection fraction 35% or less.  
**Note**  
Shared Care Model:  
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.  
**Note**  
No increase in the maximum quantity or number of units may be authorised.  
**Note**  
No increase in the maximum number of repeats may be authorised.  
**Note**  
Special Pricing Arrangements apply.  
2691P rivaroxaban 15 mg tablet, 28 1 5 .. 94.85 37.70 Xarelto BN |
| RIVAROXABAN  
**Authority required (STREAMLINED)**  
4098  
Deep vein thrombosis  
**Clinical criteria:**  
Patient must have confirmed acute symptomatic deep vein thrombosis,  
**AND**  
Patient must not have symptomatic pulmonary embolism.  
**Note** |
### BLOOD AND BLOOD FORMING ORGANS

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#### Pulmonary embolism

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note**

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

**Authority required (STREAMLINED)**

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#### Deep vein thrombosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis,
- Patient must not have symptomatic pulmonary embolism.

**Note**

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

**Note**

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

**Shared Care Model:**

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

**Authority required (STREAMLINED)**

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#### Prevention of recurrent venous thromboembolism

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

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BLOOD AND BLOOD FORMING ORGANS

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</table>

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

**Authority required (STREAMLINED)**

4268

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have confirmed acute symptomatic pulmonary embolism.

**Note**

Shared Care Model:

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

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

Note

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

Note

Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

4269

Prevention of stroke or systemic embolism

Clinical criteria:

Patient must have non-valvular atrial fibrillation, AND

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note**

Shared Care Model:

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

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

Note

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

Note

Special Pricing Arrangements apply.

2268 J

rivaroxaban 20 mg tablet, 28

1 5 .. 94.85 37.70 Xarelto BN

**Other antithrombotic agents**

**FONDAPARINUX**

**Authority required (STREAMLINED)**

2005

Prevention of venous thromboembolic events in patients undergoing major hip surgery

**Authority required (STREAMLINED)**

2006

Prevention of venous thromboembolic events in patients undergoing total knee replacement

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised
### BLOOD AND BLOOD FORMING ORGANS

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<td>140.88 *</td>
<td>37.70</td>
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**ANTIHEMORRHAGICS**

### ANTIFIBRINOLYTICS

#### Amino acids

**TRANEXAMIC ACID**

**Note**

Shared Care Model:

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

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### ANTIANEMIC PREPARATIONS

#### Iron bivalent, oral preparations

**FERROUS FUMARATE**

ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

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<th>Code</th>
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<td>8985X NP</td>
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<td>11.96</td>
<td>13.11</td>
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**FERROUS SULFATE**

ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL

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#### Iron trivalent, parenteral preparations

**IRON**

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial

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**IRON POLYMALTOSE**

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

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<td>33.03</td>
<td>a Ferrosig SI</td>
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<td></td>
<td></td>
<td>a Ferrum H AS</td>
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**IRON POLYMALTOSE Authority required (STREAMLINED)**

4302

Iron deficiency anaemia

**Treatment criteria:**

Patient must be undergoing chronic haemodialysis.

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<thead>
<tr>
<th>Code</th>
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<td>a Ferrosig SI</td>
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**IRON SUCROSE Authority required (STREAMLINED)**

4302

Iron deficiency anaemia

**Treatment criteria:**

Patient must be undergoing chronic haemodialysis.

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**Iron in combination with folic acid**


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### VITAMIN B12 AND FOLIC ACID

**Vitamin B12 (cyanocobalamin and analogues)**

**HYDROXOCOBALAMIN**

**Restricted benefit**

Pernicious anaemia

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy,
- AND
- The treatment must be for prophylaxis.

**Note**

One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

**Note**

Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2162T</td>
<td>hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>11.67</td>
<td>12.82</td>
<td>a V-B12</td>
<td>GH</td>
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<tr>
<td>9048F</td>
<td>hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>11.67</td>
<td>12.82</td>
<td>a Hydrox-B12</td>
<td>AS</td>
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**Folic acid and derivatives**

**FOLIC ACID**

**Note**

The 5 mg strength tablet should be used in malabsorption states only.

<table>
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<tr>
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<tr>
<td>1437P</td>
<td>folic acid 5 mg tablet, 100</td>
<td>2</td>
<td>1</td>
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<td>15.51</td>
<td>Megafol 5</td>
<td>AF</td>
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<tr>
<td>2958Q</td>
<td>folic acid 500 microgram tablet, 100</td>
<td>2</td>
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<td>*11.68</td>
<td>12.83</td>
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<td>PP</td>
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### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

#### BLOOD AND RELATED PRODUCTS

**Blood substitutes and plasma protein fractions**

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<tr>
<td>8444K</td>
<td>GELATIN-SUCCINYLATED</td>
<td>3</td>
<td>..</td>
<td>*46.09</td>
<td>37.70</td>
<td>Gelofusine</td>
<td>BR</td>
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<tr>
<td></td>
<td>gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag</td>
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<tr>
<td>9487H</td>
<td>PENTASTARCH + SODIUM CHLORIDE</td>
<td>3</td>
<td>..</td>
<td>*46.09</td>
<td>37.70</td>
<td>Voluven 6%</td>
<td>PK</td>
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<tr>
<td></td>
<td>HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1</td>
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#### I.V. SOLUTIONS

**Solutions for parenteral nutrition**

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<td>2245E</td>
<td>GLUCOSE</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*15.96</td>
<td>17.11</td>
<td>Baxter Healthcare Pty Ltd</td>
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<tr>
<td></td>
<td>glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<td></td>
<td></td>
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<tr>
<td>5106R</td>
<td>GLUCOSE</td>
<td>5</td>
<td>..</td>
<td>*15.96</td>
<td>17.11</td>
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<tr>
<td></td>
<td>glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
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**Solutions affecting the electrolyte balance**

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<tr>
<td>2286H</td>
<td>LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE</td>
<td>5</td>
<td>1</td>
<td>...</td>
<td>*14.66</td>
<td>15.81</td>
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<tr>
<td></td>
<td>lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag</td>
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<tr>
<td>2264E</td>
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<td>...</td>
<td>*15.21</td>
<td>16.36</td>
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<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<td>5212H</td>
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<td>...</td>
<td>...</td>
<td>*15.21</td>
<td>16.36</td>
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<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<td>2281C</td>
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<td>1</td>
<td>...</td>
<td>*23.86</td>
<td>25.01</td>
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<tr>
<td></td>
<td>sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<tr>
<td>5214K</td>
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<td>...</td>
<td>...</td>
<td>*23.86</td>
<td>25.01</td>
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<tr>
<td></td>
<td>sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<tr>
<td>3199J</td>
<td>SODIUM GLUCONATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE + SODIUM ACETATE TRihydrate + GLUCOSE</td>
<td>2</td>
<td>1</td>
<td>...</td>
<td>*22.30</td>
<td>23.45</td>
<td>Plasma-Lyte 148</td>
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<tr>
<td></td>
<td>sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td></td>
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</table>

### OTHER HEMATOLOGICAL AGENTS

**Drugs used in hereditary angioedema**

**ICATIBANT**

**Authority required**

Initial supply for anticipated emergency treatment of an acute attack of hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency who has been assessed to be at significant risk of an acute attack of hereditary angioedema by or in consultation with a clinical immunologist, respiratory physician, specialist allergist or general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The name of the Approved Pathology Authority and date of the diagnosing pathology test must be included in the authority application.

**Authority required**

Continuing supply for anticipated emergency treatment of an acute attack of hereditary angioedema, where the patient has previously been issued with an authority prescription for this drug.

**Note**

Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

<table>
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<tr>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1976B</td>
<td>ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe</td>
<td>1</td>
<td>1</td>
<td>...</td>
<td>2571.70</td>
<td>37.70</td>
<td>Firazyr</td>
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</tbody>
</table>
CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

CARDIAC GLYCOSIDES

Digitalis glycosides

DIGOXIN

Note

Shared Care Model:

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

<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium Price for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1322N</td>
<td>digoxin 250 microgram tablet, 100</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>11.05</td>
<td>12.20</td>
<td>a Sigmaxin FM</td>
</tr>
<tr>
<td>3164M</td>
<td>digoxin 50 microgram/mL oral liquid, 60 mL</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*41.46</td>
<td>37.70</td>
<td>a Lanoxin QA</td>
</tr>
<tr>
<td>2605D</td>
<td>digoxin 62.5 microgram tablet, 200</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>10.76</td>
<td>11.91</td>
<td>a Sigmaxin-PG FM</td>
</tr>
</tbody>
</table>

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

DISOPYRAMIDE

Note

Shared Care Model:

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

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<tr>
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<th>Premium Price for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2923W</td>
<td>disopyramide 100 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>29.47</td>
<td>30.62</td>
<td>Rythmodan SW</td>
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<tr>
<td>2924X</td>
<td>disopyramide 150 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>46.85</td>
<td>37.70</td>
<td>Rythmodan SW</td>
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</table>

Antiarrhythmics, class Ib

LIGNOCAINE

Note

Shared Care Model:

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

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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2876J</td>
<td>lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.93</td>
<td>31.08</td>
<td>Xylocard 500 AP</td>
</tr>
</tbody>
</table>

Antiarrhythmics, class Ic

FLECAINIDE

Restricted benefit

Serious supra-ventricular cardiac arrhythmias

Restricted benefit

Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient)

Caution

Flecainide acetate should be avoided in patients with poor cardiac function.

Note

Shared Care Model:

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium Price for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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<td>1090J</td>
<td>flecainide acetate 100 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.03</td>
<td>37.70</td>
<td>a Flecatab AF</td>
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<tr>
<td>1088G</td>
<td>flecainide acetate 50 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>38.07</td>
<td>37.70</td>
<td>a Tambocor IA</td>
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</table>

Antiarrhythmics, class III
### AMIODARONE

**Restricted benefit**
Severe cardiac arrhythmias

**Caution**
Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity. Regular monitoring of hepatic and thyroid function is recommended.

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

<table>
<thead>
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<td>2344J</td>
<td>amiodarone hydrochloride 100 mg tablet, 30</td>
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<td>5</td>
<td>..</td>
<td>11.76</td>
<td>12.91</td>
<td>a</td>
<td>Aratac 100</td>
<td>AF</td>
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<td>Amiodarone Sandoz</td>
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<td>Aratac 200</td>
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<td>Cordarone X 200</td>
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<td>Rithmik 200</td>
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<td></td>
<td></td>
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<td>Terry White Chemists Amiodarone</td>
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</tr>
</tbody>
</table>

| 2343H | amiodarone hydrochloride 200 mg tablet, 30           | 1                | 5           | ..                         | 15.66     | 16.81                       | a            | Aratac 100                        | AF                        |
|       |                                                      |                  |             |                            |           |                             |              | Cordarone X 100                  | SW                       |
|       |                                                      |                  |             |                            |           |                             |              | Amiodarone Actavis                | GN                       |
|       |                                                      |                  |             |                            |           |                             |              | Amiodarone Sandoz                 | SZ                       |
|       |                                                      |                  |             |                            |           |                             |              | Aratac 200                        | AF                       |
|       |                                                      |                  |             |                            |           |                             |              | Chem mart Amiodarone              | CH                       |
|       |                                                      |                  |             |                            |           |                             |              | Cordarone X 200                   | SW                       |
|       |                                                      |                  |             |                            |           |                             |              | GenRx Amiodarone                  | GX                       |
|       |                                                      |                  |             |                            |           |                             |              | Rithmik 200                       | QA                       |
|       |                                                      |                  |             |                            |           |                             |              | Terry White Chemists Amiodarone   | TW                       |

| 2043M | sotalol hydrochloride 160 mg tablet, 60             | 1                | 5           | ..                         | 15.81     | 16.96                       | a            | APO-Sotalol                       | TX                       |
|       |                                                      |                  |             |                            |           |                             |              | Cardol                            | AF                       |
|       |                                                      |                  |             |                            |           |                             |              | Chem mart Sotalol                 | CH                       |
|       |                                                      |                  |             |                            |           |                             |              | GenRx Sotalol                     | GX                       |
|       |                                                      |                  |             |                            |           |                             |              | Solavert                          | QA                       |
|       |                                                      |                  |             |                            |           |                             |              | Sotalol Sandoz                    | SZ                       |
|       |                                                      |                  |             |                            |           |                             |              | Terry White Chemists Sotalol      | TW                       |
|       |                                                      |                  |             |                            |           |                             |              | Sotacor                           | FM                       |

| 8398B | sotalol hydrochloride 80 mg tablet, 60              | 1                | 5           | ..                         | 10.98     | 12.13                       | a            | APO-Sotalol                       | TX                       |
|       |                                                      |                  |             |                            |           |                             |              | Cardol                            | AF                       |
|       |                                                      |                  |             |                            |           |                             |              | Chem mart Sotalol                 | CH                       |
|       |                                                      |                  |             |                            |           |                             |              | GenRx Sotalol                     | GX                       |
|       |                                                      |                  |             |                            |           |                             |              | Solavert                          | QA                       |
|       |                                                      |                  |             |                            |           |                             |              | Sotalol Sandoz                    | SZ                       |
|       |                                                      |                  |             |                            |           |                             |              | Sotacor                           | FM                       |

### SOTALOL

**Restricted benefit**
Severe cardiac arrhythmias

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

### CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

**Adrenergic and dopaminergic agents**

#### ADRENALINE

**Authority required**
Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

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<th>Premium $</th>
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<th>Safety Net $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>1</td>
<td>..</td>
<td>20.68</td>
<td>21.83</td>
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<td>LM</td>
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<td>..</td>
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<td>21.83</td>
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<td>LM</td>
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<td>37.70</td>
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<td>37.70</td>
<td>EpiPen AL</td>
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### VASODILATORS USED IN CARDIAC DISEASES

#### Organic nitrates

**GLYCERYL TRINITRATE**

- **1516T**
  - glyceryl trinitrate 10 mg/24 hours patch, 30
  - 1 5 .. .. 31.22 32.37 Transiderm-Nitro 50 NV
- **8011P**
  - glyceryl trinitrate 10 mg/24 hours patch, 30
  - 1 5 .. .. 31.22 32.37 Nitro-Dur 10 MK
- **8028M**
  - glyceryl trinitrate 10 mg/24 hours patch, 30
  - 1 5 .. .. 31.22 32.37 Minitran 10 IA
- **8026K**
  - glyceryl trinitrate 15 mg/24 hours patch, 30
  - 1 5 .. .. 31.22 32.37 Nitro-Dur 15 MK
- **8119H**
  - glyceryl trinitrate 15 mg/24 hours patch, 30
  - 1 5 .. .. 31.22 32.37 Minitran 15 IA
- **1515R**
  - glyceryl trinitrate 5 mg/24 hours patch, 30
  - 1 5 .. .. 25.41 26.56 Transiderm-Nitro 25 NV
- **8010N**
  - glyceryl trinitrate 5 mg/24 hours patch, 30
  - 1 5 .. .. 25.41 26.56 Nitro-Dur 5 MK
- **8027L**
  - glyceryl trinitrate 5 mg/24 hours patch, 30
  - 1 5 .. .. 25.41 26.56 Minitran 5 IA
- **1459T**
  - glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets
  - 1 5 .. .. 15.17 16.32 a Lycinate FM
- **5108W**
  - glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets
  - 1 5 .. .. 15.17 16.32 a Anginine Stabilised QA

**GLYCERYL TRINITRATE**

- **8171C**
  - glyceryl trinitrate 400 microgram/actuation spray, 200 actuations
  - 1 5 .. .. 20.47 21.62 Nitrolingual Pumpspray SW

**ISOSORBIDE DINITRATE**

- **2588F**
  - isosorbide dinitrate 5 mg tablet: sublingual, 100
  - 2 2 .. .. 14.90 16.05 Isordil Sublingual QA

**ISOSORBIDE MONONITRATE**

- **8273K**
  - isosorbide mononitrate 120 mg tablet: modified release, 30 tablets
  - 1 5 .. .. 16.17 17.32 a Monodur 120 mg PM
  - 8 3.03 19.20 20.32 a Imdur 120 mg AP
- **1558B**
  - isosorbide mononitrate 60 mg tablet: 1 5 .. .. 10.74 11.89 a Chem mart Isosorbide CH
### CARDIOVASCULAR SYSTEM

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**Other vasodilators used in cardiac diseases**

**NICORANDIL**

**Note**

Shared Care Model:

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

<table>
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<td>8228C</td>
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<td>Ikorel SW</td>
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<td>8229D</td>
<td>nicorandil 20 mg tablet, 60</td>
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<td>30.30</td>
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**PERHEXILINE**

**Authority required (STREAMLINED)**

1023

Angina not responding to other therapy

**Caution**

Regular monitoring of drug serum levels is recommended.

**Note**

Shared Care Model:

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

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<td>1822X</td>
<td>perhexiline maleate 100 mg tablet, 100</td>
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<td>62.96</td>
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**OTHER CARDIAC PREPARATIONS**

**Other cardiac preparations**

**IVABRADINE**

**Authority required**

Chronic heart failure

**Clinical criteria:**

Patient must be symptomatic with NYHA classes II or III,

AND

Patient must be in sinus rhythm,

AND

Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%,

AND

Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated,

AND

Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG after 5 minutes rest.

The ECG result must be documented in the patient’s medical records when treatment is initiated.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been
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**ANTIHYPERTENSIVES**

**ANTIADRENERGIC AGENTS, CENTRALLY ACTING**

**Methyldopa**

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**Imidazoline receptor agonists**

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<td>clonidine hydrochloride 150 microgram tablet, 100</td>
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<td>Catapres BY</td>
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**MOXONIDINE**

**Restricted benefit**

Hypertension in patients receiving concurrent antihypertensive therapy

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**ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING**

**Alpha-adrenoreceptor antagonists**

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**ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON Hydrazinophthalazine derivatives**

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**Pyrimidine derivatives**

**MINOXIDIL**

**Restricted benefit**

Severe refractory hypertension. Treatment must be initiated by a consultant physician

Authority required (STREAMLINED)

2759
CARDIOVASCULAR SYSTEM

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<td>2313R</td>
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<td>S</td>
<td>..</td>
<td>60.61</td>
<td>37.70</td>
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**Note**

Continuing Therapy Only:

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

### DIURETICS

#### LOW-CEILING DIURETICS, THIAZIDES

**Thiazides, plain**

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<td>..</td>
<td>21.58</td>
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#### LOW-CEILING DIURETICS, EXCL. THIAZIDES

**Sulfonamides, plain**

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<td>*17.92</td>
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#### INDAPAMIDE

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<td>20.79</td>
<td>APO-Indapamide SR TX</td>
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<td>Chem mart Indapamide SR CH</td>
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#### FRUSEMIDE

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<td>2411X</td>
<td>frusenide 10 mg/mL oral liquid, 30 mL</td>
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<td>3</td>
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<td>25.18</td>
<td>26.33</td>
<td>Lasix SW</td>
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<td>2413B</td>
<td>frusenide 20 mg/2 mL injection, 5 x 2 mL ampoules</td>
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<td>8.15</td>
<td>9.30</td>
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#### Aryloxyacetic acid derivatives

- **ETHACRYNIC ACID**
  - **Restricted benefit**
  - Patients hypersensitive to other oral diuretics

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<td>8748K</td>
<td>ethacrynic acid 25 mg tablet, 100</td>
<td>2</td>
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<td>*197.64</td>
<td>37.70</td>
<td>Edecrin FK</td>
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#### POTASSIUM-SPARING AGENTS

- **Aldosterone antagonists**
- **Eplerenone**
  - **Authority required (STREAMLINED)**
  - **2637**
  - Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.
  - The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient’s medical records when PBS-subsidised treatment is initiated.
  - **Caution**
    - Serum electrolytes should be checked regularly.
  - **Note**
    - Continuing Therapy Only:
      - For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>8879H</td>
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<td>113.11</td>
<td>37.70</td>
<td>Inspra PF</td>
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<tr>
<td>8880J</td>
<td>eplerenone 50 mg tablet, 30</td>
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<td>5</td>
<td>..</td>
<td>113.11</td>
<td>37.70</td>
<td>Inspra PF</td>
</tr>
</tbody>
</table>

- **Spironolactone**
  - **Caution**
    - Serum electrolytes should be checked regularly.
  - **Caution**
    - Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

<table>
<thead>
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<td>30.61</td>
<td>Spiractin 100 AF</td>
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<td>..</td>
<td>12.53</td>
<td>13.68</td>
<td>Aldactone PF</td>
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<td>Hydrochlorothiazide + Amiloride</td>
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#### DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

- **Low-ceiling diuretics and potassium-sparing agents**
- **Hydrochlorothiazide + Amiloride**
  - **Caution**
    - Serum electrolytes should be checked regularly.
### CARDIOVASCULAR SYSTEM

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>1486F</td>
<td>hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50</td>
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<td>1</td>
<td>..</td>
<td>*13.84</td>
<td>14.99</td>
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**HYDROCHLOROTHIAZIDE + TRIAMTERENE**

**Caution**

Serum electrolytes should be checked regularly.

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<th>No. of Rpts</th>
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<td>13.23</td>
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### PERIPHERAL VASODILATORS

#### Other peripheral vasodilators

**PHENOXYBENZAMINE**

**Authority required**

Phaeochromocytoma

**Authority required**

Neurogenic urinary retention

**Note**

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<tbody>
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<td>5</td>
<td>..</td>
<td>1164.81</td>
<td>37.70</td>
<td>Dibenyline</td>
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<td>9286R</td>
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<td>6860.58</td>
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<td>*205.24</td>
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#### BETA BLOCKING AGENTS

##### Beta blocking agents, non-selective

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<td>2961W</td>
<td>oxprenolol hydrochloride 40 mg tablet, 100</td>
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<td>48.58</td>
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<td>3065H</td>
<td>pindolol 15 mg tablet, 50</td>
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<td>16.26</td>
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<td>13.95</td>
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<td>2566C</td>
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<td>10.90</td>
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##### Beta blocking agents, selective

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<td>1081X</td>
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<td>a APO-Atenolol TX</td>
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</table>

**a**

Atenolol AN EA

Atenolol-GA GN

Atenolol GH GQ

Atenolol Sandoz SZ

Chem mart Atenolol CH

Noten AF

Tenolten 50 DO
### ATENOLOL

**Restricted benefit**

For a patient who is unable to take a solid dose form of atenolol.

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**BISOPROLOL**

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**

Continuing Therapy Only:

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

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<td>a</td>
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<td>Bicor DO</td>
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<td>Bicard 10 QA</td>
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### METOPROLOL SUCCINATE

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if...
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### NEBIVOLOL

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**

Continuing Therapy Only:

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

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### Alpha and beta blocking agents

**CARVEDILOL**

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Authority required (STREAMLINED)**

1735

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Note**

Continuing Therapy Only:

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### CARDIOVASCULAR SYSTEM

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**CALCIUM CHANNEL BLOCKERS**

**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS**

**Dihydropyridine derivatives**

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**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS**

*Phenylalkylamine derivatives*

**VERAPAMIL**

*Caution*
The myocardial depressant effects of this drug and of beta-blocking drugs are additive.
### CARDIOVASCULAR SYSTEM

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### Benzothiazepine derivatives

**DILTIAZEM**

**Caution**
The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

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**ACE INHIBITORS, PLAIN**

**ACE inhibitors, plain**

**CAPTOPRIL**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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### AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE INHIBITORS, PLAIN

ACE inhibitors, plain
## CARDIOVASCULAR SYSTEM

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### CAPTOPRIL

**Restricted benefit**

For patients unable to take a solid dose form of an ACE inhibitor

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### ENALAPRIL

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.
# CARDIOVASCULAR SYSTEM

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**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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**Lisinopril**

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**PERINDOPRIL**
### Caution
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### Note
Pharmaceutical benefits that have the form perindopril erbumine tablet 8 mg and pharmaceutical benefits that have the form perindopril arginine tablet 10 mg are equivalent for the purposes of substitution.

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### PERINDOPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Pharmaceutical benefits that have the form perindopril erbumine tablet 2 mg and pharmaceutical benefits that have the form perindopril arginine tablet 2.5 mg are equivalent for the purposes of substitution.

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### PERINDOPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Pharmaceutical benefits that have the form perindopril erbumine tablet 4 mg and pharmaceutical benefits that have the form perindopril arginine tablet 5 mg are equivalent for the purposes of substitution.

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### CARDIOVASCULAR SYSTEM

#### QUINAPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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#### RAMIPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Pharmaceutical benefits that have the form ramipril tablet 1.25 mg and pharmaceutical benefits that have the form ramipril capsule 1.25 mg are equivalent for the purposes of substitution.

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**RAMIPRIL**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

Pharmaceutical benefits that have the form ramipril tablet 2.5 mg and pharmaceutical benefits that have the form ramipril capsule 2.5 mg are equivalent for the purposes of substitution.
**CARDIOVASCULAR SYSTEM**

### ACE INHIBITORS

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**TRANDOLAPRIL**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### ACE INHIBITORS, COMBINATIONS

**ACE inhibitors and diuretics**

**ENALAPRIL + HYDROCHLOROTHIAZIDE**
CARDIOVASCULAR SYSTEM

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy. AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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**FOSINOPRIL + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy. AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**PERINDOPRIL + INDAPAMIDE**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.
QUINAPRIL + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,
AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a thiazide diuretic.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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ACE inhibitors and calcium channel blockers

LERCANDIPINE + ENALAPRIL

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,
AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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PERINDOPRIL + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,
AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease
CARDIOVASCULAR SYSTEM

**Clinical criteria:**

The treatment must not be for the initiation of therapy for coronary heart disease, AND

The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**9349C**

perindopril arginine 10 mg + amlodipine 10 mg tablet: 30 1 5 .. 40.60 37.70 a Coveram 10/10 SE

**9348B**

perindopril arginine 10 mg + amlodipine 5 mg tablet: 30 1 5 .. 33.28 34.43 a Reaptan 10/5 RX

**9347Y**

perindopril arginine 5 mg + amlodipine 10 mg tablet: 30 1 5 .. 34.79 35.94 a Coveram 5/10 SE

**9346X**

perindopril arginine 5 mg + amlodipine 5 mg tablet: 30 1 5 .. 27.45 28.60 a Reaptan 5/5 RX

**RAMIPRIL + FELODIPINE**

**Restricted benefit**

Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**2626F**

ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets 1 5 .. 13.10 14.25 Triasyn 2.5/2.5 SW

**2629J**

ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets 1 5 .. 15.39 16.54 Triasyn 5.0/5.0 SW

**TRANDOLAPRIL + VERAPAMIL**

**Restricted benefit**

Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with verapamil.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution**

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**9387C**

trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets 1 5 .. 18.74 19.89 Tarka 2/180 GO

**2857J**

trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets 1 5 .. 25.72 26.87 Tarka 4/240 GO

**ANGIOTENSIN II ANTAGONISTS, PLAIN**

**Angiotensin II antagonists, plain**

**CANDESARTAN**

**8297Q**

candesartan cilexetil 16 mg tablet: 30 1 5 .. 18.97 20.12 a Auro-Candesartan 16 DO
# CARDIOVASCULAR SYSTEM

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**EPROSARTAN**
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**LOSARTAN**

**OLMESARTAN MEDOXOMIL**

**Authority required**

Adverse effects occurring with all of the base-priced drugs

**Authority required**

Drug interactions occurring with all of the base-priced drugs

**Authority required**

Drug interactions expected to occur with all of the base-priced drugs

**Authority required**

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

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**Note**
No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

| 9371F  | valsartan 320 mg tablet, 28                        | 1               | 5           | ..        | 23.61                          | 24.76                                     | Diovan NV                      |

**ANGIOTENSIN II ANTAGONISTS, COMBINATIONS**

**Angiotensin II antagonists and diuretics**

**Candesartan + Hydrochlorothiazide**

**Restricted benefit**
Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

**AND**

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

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**Note**
No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.
## CARDIOVASCULAR SYSTEM

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### EPROSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

### IRBESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR
The condition must be inadequately controlled with a thiazide diuretic.

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**OLMESARTAN MEDI XO M I L + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND the condition must be inadequately controlled with an angiotensin II antagonist; OR the condition must be inadequately controlled with a thiazide diuretic.

- **8622T**
  - telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
  - 1 unit pack
  - 5 tablets
  - Dispensed Price for Max. Qty $: 15.02
  - Premium $: 16.17
  - Brand Name and Manufacturer: APO-Telmisartan HCTZ 40/12.5

- **8623W**
  - telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
  - 1 unit pack
  - 5 tablets
  - Dispensed Price for Max. Qty $: 27.40
  - Premium $: 28.55
  - Brand Name and Manufacturer: APO-Telmisartan HCTZ 80/12.5

**TELMISARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND the condition must be inadequately controlled with an angiotensin II antagonist; OR the condition must be inadequately controlled with a thiazide diuretic.

- **8622T**
  - telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
  - 1 unit pack
  - 5 tablets
  - Dispensed Price for Max. Qty $: 15.02
  - Premium $: 16.17
  - Brand Name and Manufacturer: APO-Telmisartan HCTZ 40/12.5

- **8623W**
  - telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
  - 1 unit pack
  - 5 tablets
  - Dispensed Price for Max. Qty $: 27.40
  - Premium $: 28.55
  - Brand Name and Manufacturer: APO-Telmisartan HCTZ 80/12.5

---

### Notes

- **Karvezide 300/25 SW**
- **KSART HCT 300/25 QA**
- **Terry White Chemists Irbesartan HCTZ**

---

### References

- Clinical criteria: The treatment must not be for the initiation of anti-hypertensive therapy, AND the condition must be inadequately controlled with an angiotensin II antagonist; OR the condition must be inadequately controlled with a thiazide diuretic.
## CARDIOVASCULAR SYSTEM

### Valsartan + Hydrochlorothiazide

#### Restricted benefit

**Hypertension**

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy,
  - AND
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9373H</td>
<td>valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>21.65</td>
<td>22.80</td>
<td></td>
<td>APO-Valsartan HCTZ 160/12.5 TX</td>
</tr>
<tr>
<td>9374J</td>
<td>valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>23.39</td>
<td>24.54</td>
<td></td>
<td>Co-Diovan 160/25 NV</td>
</tr>
<tr>
<td>9372G</td>
<td>valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>18.74</td>
<td>19.89</td>
<td></td>
<td>Co-Diovan 80/12.5 NV</td>
</tr>
</tbody>
</table>

### Valsartan + Hydrochlorothiazide

#### Restricted benefit

**Hypertension**

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy,
  - AND
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9481B</td>
<td>valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
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<td>5</td>
<td>25.36</td>
<td>26.51</td>
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<td>APO-Valsartan HCTZ 320/12.5 TX</td>
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<td>9482C</td>
<td>valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28</td>
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<td>5</td>
<td>27.10</td>
<td>28.25</td>
<td></td>
<td>Co-Diovan 320/25 NV</td>
</tr>
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</table>

### Angiotensin II antagonists and calcium channel blockers

#### Amlodipine + Valsartan

#### Restricted benefit

**Hypertension**

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy,
  - AND
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>9377M</td>
<td>amlodipine 10 mg + valsartan 160 mg tablet, 28</td>
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<td>28.98</td>
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<td>Exforge 10/160 NV</td>
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<td>Exforge 5/160 NV</td>
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<td>23.52</td>
<td>a Exforge 5/80 NV</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>a Valsartan/Amlodipine Sandoz 80/5 NM</td>
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</table>

**OLMESARTAN MEDOXOMIL + AMLODIPINE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5294P</td>
<td>olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30</td>
<td>1</td>
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<td>28.86</td>
<td>30.01</td>
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<tr>
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**TELMSARTAN + AMLODIPINE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>a Pritor/Amlodipine FI</td>
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<td>28.75</td>
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<td>a Pritor/Amlodipine FI</td>
</tr>
</tbody>
</table>

**Angiotensin II antagonists, other combinations**

**AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a
### CARDIOVASCULAR SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>30.71</td>
<td>31.86</td>
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<tr>
<td>5288H</td>
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<td>5</td>
<td>..</td>
<td>32.45</td>
<td>33.60</td>
<td>Exforge HCT 10/160/25 NV</td>
</tr>
<tr>
<td>5289J</td>
<td>amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28</td>
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<td>37.47</td>
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<td>5</td>
<td>..</td>
<td>27.17</td>
<td>28.32</td>
<td>Exforge HCT 5/160/12.5 NV</td>
</tr>
</tbody>
</table>

**OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy.

**AND**

The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>20.82</td>
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</tr>
<tr>
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<td>31.09</td>
<td>32.24</td>
<td>Sevikar HCT 40/10/12.5 MK</td>
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<tr>
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<td>5</td>
<td>..</td>
<td>33.33</td>
<td>34.48</td>
<td>Sevikar HCT 40/10/25 MK</td>
</tr>
<tr>
<td>2880N</td>
<td>olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<td>5</td>
<td>..</td>
<td>29.97</td>
<td>31.12</td>
<td>Sevikar HCT 40/5/12.5 MK</td>
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<tr>
<td>2864R</td>
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<td>5</td>
<td>..</td>
<td>32.20</td>
<td>33.35</td>
<td>Sevikar HCT 40/5/25 MK</td>
</tr>
</tbody>
</table>
GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

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

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

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

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

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

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**START HERE**

- **Have fasting lipid levels been checked?**
  - **Yes**
    - Provide lifestyle and dietary prescription and/or refer for medical nutrition therapy
    - **Has the patient received dietary therapy for at least 6 weeks?**
      - **No**
        - Patient does not qualify for PBS subsidy
      - **Yes**
        - **Have fasting lipid levels been checked?**
          - **No**
            - Measure fasting lipid levels
          - **Yes**
            - Assess patient against the Qualifying Criteria below
CARDIOVASCULAR SYSTEM

POST-DIETARY QUALIFYING CRITERIA

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

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

LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS, PLAIN
HMG-CoA reductase inhibitors

ATORVASTATIN
Restricted benefit
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty ( Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>8213G</td>
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<td>5</td>
<td>..</td>
<td>11.41</td>
<td>12.56</td>
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| Brand Name and Manufacturer | |
|----------------------------| |
| APO-Atorvastatin TX | |
| NPE-Atorvachol GN | |
| A-Atorvastatin AN EA | |
| A-Atorvastatin GH GQ | |
| A-Atorvastatin Pfizer FZ | |
| A-Atorvastatin Sandoz SZ | |
| A-Atorvastatin SCP 10 RZ | |
| A-Atorvastatin SZ HX | |
| A-Blooms the Chemist Atorvastatin IB | |
| A-Chem mart Atorvastatin CH | |
| A-Lipitor PF | |
| A-Lorstat 10 AF | |
| A-Terry White Chemists Atorvastatin TW | |
### ATORVASTATIN

**Restricted benefit**  
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements  

**Note**  
No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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**ATORVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

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**FLUVASTATIN**

*Restricted benefit*

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs
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**PRAVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
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**ROSUVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

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

**Note**

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

**Note**

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**ROSUVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

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

AND

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

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**ROSVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

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## Cardiovascular System

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### Simvastatin

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
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**Fibrates**

**FENOFLURATE**

*Restricted benefit*

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history.
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**FENOFOBRATE**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**GEMFIBROZIL**

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Note**

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**Bile acid sequestrants**
**Other lipid modifying agents**

**EZETIMIBE**

**Authority required (STREAMLINED)**

3724

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have coronary heart disease. Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin and who have diabetes mellitus. Inadequate control with a statin is defined as follows:

   a. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

**Authority required (STREAMLINED)**

3725

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

**Authority required (STREAMLINED)**

3726

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3727 Treatments, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have heterozygous familial hypercholesterolemia. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

3728 Treatments, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have symptomatic cerebrovascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

3729 Treatments, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have family history of coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

3730 Treatments, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have hypertension. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the
cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED) 1989

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

Authority required (STREAMLINED) 3731

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced because the patient developed a clinically important product-related adverse event during treatment with a statin.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Authority required (STREAMLINED) 1991

Homozygous sitosterolaemia.

Authority required (STREAMLINED) 2438

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin).

Note

Continuing Therapy Only:

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

LIPID MODIFYING AGENTS, COMBINATIONS

HMG CoA reductase inhibitors in combination with other lipid modifying agents

ATORVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED) 4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED) 4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise, AND
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4086
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have diabetes mellitus.

AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND
Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4069
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have diabetes mellitus.

AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND
Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4096
Hypercholesterolaemia

**Clinical criteria:**
Inadequate control with a statin is defined as follows:

Patient must have hypertension.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), and

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4120
Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), and

 Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4121
Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), and

 Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097
Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Authority required (STREAMLINED)

Hypercholesterolaemia

Clinical criteria:

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

AND

Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Note

Continuing Therapy Only:

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

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,
### CARDIOVASCULAR SYSTEM

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**Note**

**Continuing Therapy Only:**

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

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**EZETIMIBE + SIMVASTATIN**

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

**AND**

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

**AND**

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
### 4120 Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4121 Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4097 Hypercholesterolaemia

**Clinical criteria:**

Patient must have homozygous familial hypercholesterolaemia,

**AND**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

### 4147 Hypercholesterolaemia

**Clinical criteria:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

**AND**

Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Note

Continuing Therapy Only:

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

9483D

ezetimibe 10 mg + simvastatin 10 mg tablet, 30

Dispensed Price for Max. Qty $ 73.41

Maximum Recordable Value for Safety Net $ 37.70

Brand Name and Manufacturer Vytorin MK

9484E

ezetimibe 10 mg + simvastatin 20 mg tablet, 30

Dispensed Price for Max. Qty $ 74.34

Maximum Recordable Value for Safety Net $ 37.70

Brand Name and Manufacturer Vytorin MK

EZETIMIBE + SIMVASTATIN

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,
Inadequate control with a statin is defined as follows:

Patient must have symptomatic cerebrovascular disease.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia
**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

**Inadequate control with a statin is defined as follows:**

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

**Inadequate control with a statin is defined as follows:**

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097

Hypercholesterolaemia

**Clinical criteria:**

Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Note**

**Continuing Therapy Only:**

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

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</table>
The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4085
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4086
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4069
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise.

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
CARDIOVASCULAR SYSTEM

Authority required (STREAMLINED)
4121
Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,
AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),
AND
Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)
4097
Hypercholesterolaemia

Clinical criteria:
Patient must have homozygous familial hypercholesterolaemia,
AND
Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

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

ROSUVASTATIN (&) EZETIMIBE
Authority required (STREAMLINED)
4068
Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,
AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),
AND
Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Inadequate control with a statin is defined as follows:

- Patient must have heterozygous familial hypercholesterolaemia.

AND

- The treatment must be in conjunction with dietary therapy and exercise.

AND

- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise.

AND

- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise.

AND

- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin).

AND

- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4096
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4120
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4121
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
**Cardiovascular System**

**Hypercholesterolaemia**

**Clinical criteria:**
- Patient must have homozygous familial hypercholesterolaemia,
- AND
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required [STREAMLINED]**

4097

Hypercholesterolaemia

**Clinical criteria:**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),
- AND
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:
- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Note**

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

**HMG CoA reductase inhibitors, other combinations**

**AMLODIPINE + ATORVASTATIN**

**Restricted benefit**

For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate.

**Restricted benefit**

For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.
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<th>No. of Rpts</th>
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## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

#### Antibiotics

**NYSTATIN**

*Authority required (STREAMLINED)*

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*Imidazole and triazole derivatives*

**KETOCONAZOLE**

*Authority required (STREAMLINED)*

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<td>ketoconazole 2% (20 mg/g) cream, 30 g</td>
<td>‡1</td>
<td>2</td>
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<td>23.46</td>
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<td>1574W</td>
<td>ketoconazole 2% (20 mg/g) shampoo, 60 mL</td>
<td>‡1</td>
<td>1</td>
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<td>18.65</td>
<td>19.80</td>
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**MICONAZOLE**

*Authority required (STREAMLINED)*

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<td>9031H</td>
<td>miconazole 2% solution, 30 mL</td>
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<td>9028E</td>
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**Other antifungals for topical use**

**TERBINAFINE**

*Authority required (STREAMLINED)*

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### ANTIFUNGALS FOR SYSTEMIC USE

#### Antifungals for systemic use

**GRISEOFULVIN**

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<td>2982Y</td>
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**TERBINAFINE**

*Authority required*

Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed

*Authority required*

Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed
**DERMATOLOGICALS**

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<tr>
<td></td>
<td>Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old.</td>
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<td>No applications for increased maximum quantities and/or repeats will be authorised.</td>
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<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<td>Chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy</td>
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## DERMATOLOGICALS

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<th>Brand Name and Manufacturer</th>
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<td>5276Q</td>
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<td>42.23</td>
<td>37.70</td>
<td>Daivobet 50/500 gel</td>
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<td>The condition must be on the patient’s scalp,</td>
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<td></td>
<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy, <strong>AND</strong> Patient must require more than 30 grams of the product per month.</td>
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<td>74.88</td>
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<td>Daivobet 50/500 gel</td>
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<td><strong>ANTIPSORIATICS FOR SYSTEMIC USE</strong></td>
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<td><em>Retinoids for treatment of psoriasis</em></td>
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<td><strong>Caution</strong></td>
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<td>This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.</td>
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<td>Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.</td>
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<td>acitretin 10 mg capsule, 100</td>
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<td>174.32</td>
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<td>37.70</td>
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### ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

#### CHEMOTHERAPEUTICS FOR TOPICAL USE

**Sulfonamides**
## DERMATOLOGICALS

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<td>Prevention and treatment of infection in partial or full skin thickness loss due to burns</td>
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<td>Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa</td>
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<td>..</td>
<td>19.49</td>
<td>20.64</td>
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<td>Flamazine SN</td>
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## CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

#### Corticosteroids, weak (group I)

**HYDROCORTISONE ACETATE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>2887Y</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 30 g</td>
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<td>5111B</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 30 g</td>
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<td>..</td>
<td>2.69</td>
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### Corticosteroids, moderately potent (group II)

**TRIAMCINOLONE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

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<td>2117K</td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g</td>
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<td>*14.74</td>
<td>15.89</td>
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<td>a Tricortone FM</td>
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<td>triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g</td>
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<td>a Tricortone FM</td>
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### Corticosteroids, potent (group III)

**BETAMETHASONE DIPROPIONATE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

**Note**

Continuing Therapy Only:

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

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<td>14.63</td>
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<td>NP</td>
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<td>Eleuphat FR</td>
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<td>methylprednisolone aceponate 0.1% (1 mg/g) cream, 15 g</td>
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<td>NP</td>
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<td>16.14</td>
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<td>15.42</td>
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<td>8043H</td>
<td>mometasone furoate 0.1% lotion, 30 mL</td>
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<td>15.58</td>
<td>16.73</td>
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## DERMATOLOGICALS

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<th>Brand Name and Manufacturer</th>
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<td>a Zatamil EO</td>
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<td>a Elocon MK</td>
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### Corticosteroids, very potent (group IV)

**CLOBETASOL**

**Authority required**

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be aged 18 years or older.

<table>
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<td>a Elocon MK</td>
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</table>

### ANTI-ACNE PREPARATIONS

#### ANTI-ACNE PREPARATIONS FOR TOPICAL USE

**Retinoids for topical use in acne**

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**

Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris

<table>
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</thead>
<tbody>
<tr>
<td>8954G</td>
<td>adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g</td>
<td>$3.72</td>
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<td>48.98</td>
<td>37.70</td>
<td>a Epiduo GA</td>
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</table>

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**

Maintenance treatment of severe acne vulgaris

**Note**

Continuing Therapy Only:

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

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<td>48.98</td>
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#### ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

**Retinoids for treatment of acne**

**ISOTRETINOIN**

**Authority required (STREAMLINED)**

Severe cystic acne not responsive to other therapy

**Caution**

This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

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### OTHER DERMATOLOGICAL PREPARATIONS

#### OTHER DERMATOLOGICAL PREPARATIONS

**Agents for dermatitis, excluding corticosteroids**

**PIMECROLIMUS**

**Authority required**

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:

- (i) perioral dermatitis;
- (ii) periorbital dermatitis;
- (iii) rosacea;
- (iv) epidermal atrophy;
- (v) dermal atrophy;
- (vi) allergy to topical corticosteroids;
- (vii) cataracts;
- (viii) glaucoma;
- (ix) raised intraocular pressure

**Authority required**

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

- (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
- (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
- (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
- (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

8802G pimecrolimus 1% (10 mg/g) cream, 15 g 1 1 .. 34.13 35.28 Elidel HM

#### Other dermatologicals

**DAPSONE**

**Note**

Shared Care Model:

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

1272Y dapsone 100 mg tablet, 100 1 1 .. 114.18 37.70 Link Medical Products Pty Ltd LM

8801F dapsone 25 mg tablet, 100 1 1 .. 100.92 37.70 Link Medical Products Pty Ltd LM

**IMIQUIMOD**

**Authority required**

Superficial basal cell carcinoma

**Clinical criteria:**
The condition must be previously untreated,
AND
The condition must be confirmed by biopsy,
AND
Patient must have normal immune function,
AND
The condition must not be suitable for treatment with surgical excision; OR
The condition must not be suitable for treatment with cryotherapy; OR
The condition must not be suitable for treatment with curettage with diathermy,
AND
Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**Note**
The patient or carer must be able to understand and administer the imiquimod dosing regimen.

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

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

**Note**
Treatment of recurrent (previously treated) lesions will not be authorised.

**Note**
Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2546B</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
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<td>135.72</td>
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### OTHER GYNECOLOGICALS

#### OXYTOCICS

**Prostaglandins**

|Mifepristone (&) Misoprostol**  
**Authority required**

Termination of an intra-uterine pregnancy

Clinical criteria:
The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

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

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

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#### CONTRACEPTIVES FOR TOPICAL USE

**Intrauterine contraceptives**

| Levonorgestrel**  
**Restricted benefit**

Contraception

Restricted benefit
Idiopathic menorrhagia where oral treatments are ineffective

Restricted benefit
Idiopathic menorrhagia where oral treatments are contraindicated

<table>
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<td>8633J</td>
<td>Levonorgestrel 52 mg drug delivery system: intrauterine, 1 system</td>
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#### OTHER GYNECOLOGICALS

**Prolactine inhibitors**

| Bromocriptine**  
**Restricted benefit**  
Acromegaly

Restricted benefit
Parkinson’s disease

Restricted benefit
Pathological hyperprolactinaemia where surgery is not indicated

Restricted benefit
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

Restricted benefit
Pathological hyperprolactinaemia where radiotherapy is not indicated

Restricted benefit
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

**Note**
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**
For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

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SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

Progestogens and estrogens, fixed combinations

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<th>No. of Rpts</th>
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<tr>
<td>1394J</td>
<td>ETHINYLESTRODIOL + LEVONORGESTREL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>15.64</td>
<td>16.79</td>
<td>a Monofeme 28 FZ</td>
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<td></td>
<td>ethinylestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>b Eleanor 150/30 ED EA</td>
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<td></td>
<td></td>
<td>b Evelyn 150/30 ED GQ</td>
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<td></td>
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<td>b Femme-Tab ED 30/150 AE</td>
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<td>..</td>
<td>15.64</td>
<td>16.79</td>
<td>16.79</td>
<td>b Leven ED SY b Micronelle 30 ED TX b Microgonyn 30 ED BN a Nordette 28 PF</td>
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<td>2416E</td>
<td>ethinylestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
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<td>16.79</td>
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<td>16.80</td>
<td>17.95</td>
<td>17.95</td>
<td>a Norimin-1 28 Day FZ a Brevinor-1 PF a Norimin 28 Day FZ</td>
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<td>17.95</td>
<td>17.95</td>
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<td>17.95</td>
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<td>Norinyl-1/28 PF</td>
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**Progestogens and estrogens, sequential preparations**

ETHINYLESTRADIOL + LEVONORGESTREL

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**Progestogens**

ETONOGESTREL

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LEVONORGESTREL

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<td>2913H</td>
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<td>17.66</td>
<td>18.81</td>
<td>18.81</td>
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MEDROXYPROGESTERONE

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<td>3118D</td>
<td>medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial</td>
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<td>23.01</td>
<td>24.16</td>
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NORETHISTERONE

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<td>1967M</td>
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<td>17.95</td>
<td>17.95</td>
<td>Micronor JC Noriday 28 Day PF</td>
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**ANDROGENS**

3-oxoandrostren (4) derivatives

TESTOSTERONE
### Authority required

**Androgen deficiency**

**Clinical criteria:**
Patient must have an established pituitary or testicular disorder.

**Population criteria:**
Patient must be male.

**Authority required**

Androgen deficiency

**Clinical criteria:**
Patient must not have established pituitary or testicular disorders other than ageing.

**Population criteria:**
Patient must be male,
AND
Patient must be aged 40 years or older.

Androgen deficiency is defined as:
(i) testosterone level of less than 8 nmol per litre; OR
(ii) testosterone level between 8 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men)

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

**Authority required**

**Micropenis**

**Population criteria:**
Patient must be male,
AND
Patient must be under 18 years of age.

**Authority required**

**Pubertal induction**

**Population criteria:**
Patient must be male,
AND
Patient must be under 18 years of age.

**Authority required**

**Constitutional delay of growth or puberty**

**Population criteria:**
Patient must be male,
AND
Patient must be under 18 years of age.

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<thead>
<tr>
<th>Code</th>
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<th>Dispensed Price for Max. Qty $</th>
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<td>Testogel HB</td>
<td>95.46</td>
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<td>5</td>
<td>30 x 5 g sachets</td>
<td>testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets</td>
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<td>2341F</td>
<td>Axiron LY</td>
<td>82.79</td>
<td>37.70</td>
<td>96.18</td>
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<td>60 actuations</td>
<td>testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations</td>
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<td>Androderm GN</td>
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<td>37.70</td>
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<td>60 patch</td>
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**TESTOSTERONE ENANTHATE**

**Authority required**

Androgen deficiency

**Clinical criteria:**
Patient must have an established pituitary or testicular disorder.

**Population criteria:**
Patient must be male.
Androgen deficiency
Clinical criteria:
Patient must not have established pituitary or testicular disorders other than ageing.

Population criteria:
Patient must be male,
AND
Patient must be aged 40 years or older.

Androgen deficiency is defined as:
(i) testosterone level of less than 8 nmol per litre; OR
(ii) testosterone level between 8 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men)

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

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**TESTOSTERONE UNDECANOATE**

**Authority required**
Androgen deficiency

Clinical criteria:
Patient must have an established pituitary or testicular disorder.

Population criteria:
Patient must be male.

**Authority required**
Androgen deficiency

Clinical criteria:
Patient must not have established pituitary or testicular disorders other than ageing.

Population criteria:
Patient must be male,
AND
Patient must be aged 40 years or older.

Androgen deficiency is defined as:
(i) testosterone level of less than 8 nmol per litre; OR
(ii) testosterone level between 8 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men)
Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

**Authority required**

**Micropenis**

Population criteria:
Patient must be male,

**AND**

Patient must be under 18 years of age.

**Authority required**

**Pubertal induction**

Population criteria:
Patient must be male,

**AND**

Patient must be under 18 years of age.

**Authority required**

**Constitutional delay of growth or puberty**

Population criteria:
Patient must be male,

**AND**

Patient must be under 18 years of age.

### ESTROGENS

**Natural and semisynthetic estrogens, plain**

#### OESTRADIOL

**Note**
Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**Note**
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### GENITO URINARY SYSTEM AND SEX HORMONES

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## Progestogens and Estrogens in Combination

### Progestogens and Estrogens, Fixed Combinations

#### Nor ethisterone Acetate + Oestradiol

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#### Oestradiol + Dydrogesterone

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### Progestogens and Estrogens, Sequential Preparations

#### Nor ethisterone Acetate + Oestradiol (&) Oestradiol

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#### Oestradiol (&) Oestradiol + Dydrogesterone

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## Gonadotropins and Other Ovulation Stimulants

### Gonadotropins

**Follitropin Alfa**
*Restricted benefit*
Anovulatory infertility

*Restricted benefit*
GENITO URINARY SYSTEM AND SEX HORMONES

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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<td>follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>...</td>
<td>*493.84</td>
<td>37.70</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>8714P</td>
<td>follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge</td>
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<td>5</td>
<td>...</td>
<td>*737.41</td>
<td>37.70</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>8715Q</td>
<td>follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>2</td>
<td>5</td>
<td>...</td>
<td>*980.94</td>
<td>37.70</td>
<td>Gonal-f Pen SG</td>
</tr>
</tbody>
</table>

**FOLLITROPIN BETA**

**Restricted benefit**

Anovulatory infertility

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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<tr>
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<tr>
<td>8565T</td>
<td>follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge</td>
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<td>5</td>
<td>...</td>
<td>*509.95</td>
<td>37.70</td>
<td>Puregon 300 IU/0.36 mL MK</td>
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<tr>
<td>8566W</td>
<td>follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge</td>
<td>2</td>
<td>5</td>
<td>...</td>
<td>*661.40</td>
<td>37.70</td>
<td>Puregon 600 IU/0.72 mL MK</td>
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<td>8871X</td>
<td>follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge</td>
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<td>...</td>
<td>*979.92</td>
<td>37.70</td>
<td>Puregon 900 IU/1.08 mL MK</td>
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</tbody>
</table>

**GONADOTROPHIN CHORIONIC HUMAN**

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

For the treatment of infertility in males associated with isolated luteinising hormone deficiency

**Restricted benefit**

For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation

**Restricted benefit**

For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.
Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Ovulation stimulants, synthetic**

**CLOMIPHENE**

*Restricted benefit*

Anovulatory infertility

*Restricted benefit*

Patients undergoing in-vitro fertilisation

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

### ANTIANDROGENS

**Antiandrogens, plain**

**CYPROTERONE**

*Authority required (STREAMLINED)*

1014

Advanced carcinoma of the prostate

*Authority required (STREAMLINED)*

1404

To reduce drive in sexual deviations in males

<table>
<thead>
<tr>
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<td>5</td>
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<td>36.00</td>
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<td>37.70</td>
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<td>37.70</td>
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<td>28.94</td>
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**CYPROTERONE**

*Authority required (STREAMLINED)*

1230

Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation)

**Caution**

This drug should not be used during pregnancy as it may result in feminisation of the male foetus.
GENITO URINARY SYSTEM AND SEX HORMONES

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Antigonadotropins and similar agents

DANAZOL
Authority required (STREAMLINED)
1090
Endometriosis, visually proven

Authority required (STREAMLINED)
1151
Hereditary angio-oedema

Authority required (STREAMLINED)
2639
Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information)

Authority required (STREAMLINED)
2640
Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information)

Caution
Pregnancy must be excluded prior to administration of this drug.

1285P
danazol 100 mg capsule, 100
1 5 .. 58.92 37.70 Azol 100 AF

1287R
danazol 200 mg capsule, 100
1 5 .. 87.31 37.70 Azol 200 AF

GESTRINONE
Authority required (STREAMLINED)
3652
Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy may be prescribed)

8015W
gestrinone 2.5 mg capsule, 8
1 5 .. 82.15 37.70 Dimetriose SW

Antiprogestogens

MIFEPRISTONE (&) MISOPROSTOL
Authority required
Termination of an intra-uterine pregnancy

Clinical criteria:
The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

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

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

10211K
mifepristone 200 mg tablet [1] (&)
misoprostol 200 microgram tablet [4], 1 pack
‡1 .. .. 321.38 37.70 MS-2 Step XH

UROLOGICALS

UROLOGICALS

Drugs for urinary frequency and incontinence

OXYBUTYNIN
Restricted benefit
Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin

9454N
oxybutynin 3.9 mg/24 hours patch, 8
‡1 5 .. 35.57 36.72 Oxytrol GN
GENITO URINARY SYSTEM AND SEX HORMONES

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<td>14.34</td>
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<td>1164.81</td>
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<td>1166J NP</td>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 30</td>
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<td>5</td>
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<td>*205.24</td>
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<td>DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY</td>
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<td>Alpha-adrenoreceptor antagonists</td>
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<td>Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist</td>
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<td>dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30</td>
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<td>5</td>
<td>...</td>
<td>35.63</td>
<td>36.78</td>
<td>Duodart 500ug/400ug GK</td>
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<td>Testosterone-5-alpha reductase inhibitors</td>
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<td></td>
<td>DUTASTERIDE</td>
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<td>Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist</td>
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<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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GENITO URINARY SYSTEM AND SEX HORMONES
# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

#### ACTH

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<td>2832C</td>
<td>TETRACOSACTRIN modified release, 1 x 1 mL ampoule</td>
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<td>5</td>
<td>..</td>
<td>*71.61</td>
<td>37.70</td>
<td>Synacthen Depot 1 mg/1 mL NV</td>
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#### Thyrotropin

**Authority required (STREAMLINED)**

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<td>1901.76</td>
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<td>Thyrogen GZ</td>
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### POSTERIOR PITUITARY LOBE HORMONES

#### Vasopressin and analogues

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<td>2641</td>
<td>DESMOPRESSIN</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>71.19</td>
<td>37.70</td>
<td>Minirin Melt FP</td>
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<tr>
<td>2642</td>
<td>DESMOPRESSIN</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>116.28</td>
<td>37.70</td>
<td>Minirin Melt FP</td>
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### DESSMOPRESSIN

**Authority required (STREAMLINED)**

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<tr>
<th>Code</th>
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### DESSMOPRESSIN

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<td>8662X</td>
<td>DESMOPRESSIN</td>
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### Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins

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<th>Brand Name and Manufacturer</th>
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<td>8712M</td>
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<td>84.07</td>
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<td>Minirin Nasal Spray</td>
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<td>2641</td>
<td>Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm</td>
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<tr>
<td>2642</td>
<td>Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient’s medical records when treatment is initiated</td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
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<td>Nafarelin 200 microgram/actuation nasal spray, 60 actuations</td>
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**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

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### HYDROCORTISONE

**Note**

Continuing Therapy Only:

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

### METHYLPREDNISOLONE

**Note**

Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.

### METHYLPREDNISOLONE

**Note**

Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.
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**PREDNISOLONE SODIUM PHOSPHATE**

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<td>26.49</td>
<td>QA Kenacort-A10</td>
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**TRIAMCINOLONE**

**Restricted benefit**

Alopecia areata

**Restricted benefit**

For local intra-articular or peri-articular infiltration

**Restricted benefit**

Granulomata, dermal

**Restricted benefit**

Keloid

**Restricted benefit**

Lichen planus hypertrophic

**Restricted benefit**

Lichen simplex chronicus

**Restricted benefit**

Lupus erythematosus, chronic discoid

**Restricted benefit**

Necrobiosis lipoidica

**Restricted benefit**

Psoriasis

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

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<td>26.49</td>
<td>Kenacort-A10</td>
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**THYROID THERAPY**

**THYROID PREPARATIONS**

**Thyroid hormones**

**LIOTHYRONINE**

**Authority required (STREAMLINED)**

1219

Management of patients with thyroid cancer

**Authority required (STREAMLINED)**

1658

Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium

**Authority required (STREAMLINED)**

1859

Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium

**Authority required (STREAMLINED)**

1182

Initiation of thyroid therapy in severely hypothyroid patients

**Note**

Continuing Therapy Only:

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

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<th>Premium $</th>
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<tr>
<td>2318B NP</td>
<td>liothyronine sodium 20 microgram tablet, 100</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>83.87</td>
<td>37.70</td>
<td>Tertroxin</td>
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</table>

**THYROXINE**

**Note**

Continuing Therapy Only:

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<td>2175L NP</td>
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<td>24.32</td>
<td>25.47</td>
<td>a Eutroxsig</td>
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<tr>
<td>2173J NP</td>
<td>thyroxine sodium 200 microgram tablet, 200</td>
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<td>1</td>
<td>..</td>
<td>26.53</td>
<td>25.47</td>
<td>a Oroxine</td>
</tr>
<tr>
<td>2174K NP</td>
<td>thyroxine sodium 50 microgram tablet, 200</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>29.56</td>
<td>28.50</td>
<td>a Eutroxsig</td>
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<tr>
<td>9287T NP</td>
<td>thyroxine sodium 75 microgram tablet, 200</td>
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<td>1</td>
<td>..</td>
<td>25.91</td>
<td>24.86</td>
<td>a Oroxine</td>
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**ANTITHYROID PREPARATIONS**

**Thiouracils**

**PROPYLTHIOURACIL**

**Note**

Continuing Therapy Only:

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

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<tr>
<td>1955X NP</td>
<td>propylthiouracil 50 mg tablet, 100</td>
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<td>*49.98</td>
<td>37.70</td>
<td>PTU</td>
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**Sulfur-containing imidazole derivatives**

**CARBIMAZOLE**

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

1153Q  
NP  
carbimazole 5 mg tablet, 100  
2  
2  
..  
*31.38  
32.53  
Carbimazol ARISTO  
PQ  
Neo-Mercazole  
LM

GLUCAGON HYDROCHLORIDE  

Glycogenolytic hormones

1449G  
NP  
glucagon hydrochloride 1 mg injection  
[1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack  
1  
1  
..  
50.55  
37.70  
GlucaGen Hypokit  
NO

5105Q  
DP  
glucagon hydrochloride 1 mg injection  
[1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack  
1  
..  
..  
50.55  
37.70  
GlucaGen Hypokit  
NO

PARATHYROID HORMONES AND ANALOGUES  

Parathyroid hormones and analogues

TERIPARATIDE  

Authority required
Severe established osteoporosis
Treatment Phase: Initial treatment
Clinical criteria:
Patient must be at very high risk of fracture,
AND
Patient must have a bone mineral density (BMD) T-score of -3.0 or less,
AND
Patient must have had 2 or more fractures due to minimal trauma,
AND
Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,
AND
The treatment must be the sole PBS-subsidised agent,
AND
The treatment must not exceed a lifetime maximum of 18 months therapy.
Treatment criteria:
Must be treated by a specialist; OR
Must be treated by a consultant physician.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.
If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.
Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.
Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.
### SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Max. Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9411H</td>
<td>teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>438.71</td>
<td>37.70</td>
<td>Forteo</td>
</tr>
</tbody>
</table>

**Note**
Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

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

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

**Note**
Special Pricing Arrangements apply.

**Authority required**
Severe established osteoporosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug.

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note**
Up to a maximum of 18 pens will be reimbursed through the PBS.

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

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

**Note**
Special Pricing Arrangements apply.

### ANTI-PARATHYROID AGENTS

#### Calcitonin preparations

**SALCATONIN**

**Authority required (STREAMLINED)**

3256

Symptomatic Paget disease of bone

**Authority required (STREAMLINED)**

1412

Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia

**Note**
The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer’s packs. The pack size for both strengths is five ampoules.

**Note**
Continuing Therapy Only:

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

2997R

**NP**
salcatonin 100 international units/mL injection, 5 x 1 mL ampoules

**Other anti-parathyroid agents**

**CINACALCET**

**Authority required (STREAMLINED)**

3673

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment

**Authority required (STREAMLINED)**

3672

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment

**Note**
During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses...
between 30 and 180 mg per day according to the patient’s response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

**Note**
Special Pricing Arrangements apply.

**Note**
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
## ANTIINFECTIVES FOR SYSTEMIC USE
### ANTIBACTERIALS FOR SYSTEMIC USE
#### TETRACYCLINES

**Tetracyclines**

**DOXYCYCLINE**

**Restricted benefit**

Urethritis

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2715X</td>
<td>doxycycline 100 mg capsule: modified release, 21 capsules</td>
<td>3</td>
<td>..</td>
<td>1.93</td>
<td>11.96</td>
<td>11.18</td>
<td>a Mayne Pharma YT Doxycline</td>
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<tr>
<td>10176N</td>
<td>doxycycline 100 mg tablet, 21</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.72</td>
<td>11.18</td>
<td>a Doryx AN EA</td>
</tr>
<tr>
<td>1800R</td>
<td>doxycycline 100 mg tablet, 21</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>10.03</td>
<td>11.18</td>
<td>a GenRx Doxycycline GX</td>
</tr>
<tr>
<td>2714W</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*10.03</td>
<td>11.18</td>
<td>a Doxsig QA</td>
</tr>
<tr>
<td>9108J</td>
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<td>3</td>
<td>..</td>
<td>..</td>
<td>*10.03</td>
<td>11.18</td>
<td>a Doxy-100 GN</td>
</tr>
</tbody>
</table>

**DOXYCYCLINE**

**Restricted benefit**

Pelvic inflammatory disease

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

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<tr>
<td>2703G</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>4</td>
<td>..</td>
<td>3.36</td>
<td>*14.48</td>
<td>12.27</td>
<td>a Mayne Pharma YT Doxycline</td>
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<tr>
<td>2702F</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>4</td>
<td>..</td>
<td>8.00</td>
<td>*19.12</td>
<td>12.27</td>
<td>a Doxig QA</td>
</tr>
<tr>
<td>9107H</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>4</td>
<td>..</td>
<td>..</td>
<td>*11.12</td>
<td>12.27</td>
<td>a Chem mart Doxycycline CH</td>
</tr>
</tbody>
</table>

**DOXYCYCLINE**

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2708M</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>1</td>
<td>1</td>
<td>0.84</td>
<td>8.69</td>
<td>9.00</td>
<td>a Mayne Pharma YT Doxycline</td>
</tr>
<tr>
<td>3322W</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>1</td>
<td>..</td>
<td>0.84</td>
<td>8.69</td>
<td>9.00</td>
<td>a Mayne Pharma YT Doxycline</td>
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<tr>
<td>2709N</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>1</td>
<td>1</td>
<td>2.00</td>
<td>9.85</td>
<td>9.00</td>
<td>a Doxig QA</td>
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<tbody>
<tr>
<td>3322W</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>1</td>
<td>..</td>
<td>2.00</td>
<td>9.85</td>
<td>9.00</td>
<td>a Doxy-100 GN</td>
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## ANTIINFECTIVES FOR SYSTEMIC USE

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<td>3321T</td>
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<td>9.00</td>
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<td>..</td>
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<td>Terry White Chemists TW</td>
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<td>9105F</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>1</td>
<td>1</td>
<td>7.85</td>
<td>9.00</td>
<td></td>
<td>Mayne Pharma YT</td>
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<td>Doxycycline Sandoz HX</td>
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<td>GenRx Doxycycline GX</td>
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<td>Terry White Chemists TW</td>
</tr>
</tbody>
</table>

### DOXYCYCLINE

**Restricted benefit**

**Bronchiectasis**

**Population criteria:**

Patient must be aged 8 years or older.

**Restricted benefit**

**Chronic bronchitis**

**Population criteria:**

Patient must be aged 8 years or older.

**Restricted benefit**

Severe acne

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

### MINOCYCLINE

**Restricted benefit**

Severe acne not responding to other tetracyclines

**Caution**

There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

### BETA-LACTAM ANTIBACTERIALS, PENICILLINS

*Penicillins with extended spectrum*
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8581P NP</td>
<td>Amoxycillin 1 g tablet, 14</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>8.34</td>
<td>9.49</td>
<td>a Amoxycillin Sandoz BG</td>
</tr>
<tr>
<td>1886G NP</td>
<td>Amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>#10.07</td>
<td>11.57</td>
<td>a Alphmax 125 AF</td>
</tr>
<tr>
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**AMOXICILLIN**

**Authority required**

Treatment of infections suspected or proven to be due to a susceptible organism in patients who require a liquid formulation and in whom the syrup formulations are unsuitable

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**Beta-lactamase sensitive penicillins**

**BENZATHINE BENZYL-PENICILLIN**

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### Antiinfectives for Systemic Use

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#### Phenoxymethyl Penicillin

**Restricted benefit**

- **Prophylaxis of recurrent streptococcal infections (including rheumatic fever)**

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<td>1705R</td>
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#### Procaine Penicillin

**Restricted benefit**

- **Serious staphylococcal infections**

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<td>1794K</td>
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#### Beta-lactamase Resistant Penicillins

#### Dicloxacillin

**Restricted benefit**

- **Serious staphylococcal infections**

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<td>5096F</td>
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<td>8121K</td>
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#### Flucloxacillin

**Caution**

- Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

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<td>1524F</td>
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#### Flucloxacillin

**Restricted benefit**

- **Serious staphylococcal infections**

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<td>9149M</td>
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<td>1526H</td>
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</table>

*a Flubiclox GN
*a Flucil AS
*a Hospira Pty Limited HH
*a Fluclox GN
*a Flucil AS
*a Hospira Pty Limited HH
*a Fluclox GN
*a Flucil AS
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<td>9150N</td>
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<td>5091Y</td>
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<td>16.75</td>
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**Combinations of penicillins, incl. beta-lactamase inhibitors**

**AMOXYCILLIN + CLAVULANIC ACID**

**Restricted benefit**
Infections where resistance to amoxycillin is suspected

**Restricted benefit**
Infections where resistance to amoxycillin is proven

**Caution**
Hepatotoxicity has been reported with this drug.

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>＄13.65</td>
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<tr>
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### TICARCLIN + CLAVULANIC ACID

#### Restricted benefit
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit
Septicaemia, suspected

#### Restricted benefit
Septicaemia, proven

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

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**TICARCLIN + CLAVULANIC ACID**

**Restricted benefit**
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.

**Restricted benefit**
Septicaemia, suspected.

**Restricted benefit**
Septicaemia, proven.

**Note**
Shared Care Model:
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<td><strong>TICARCILLIN + CLAVULANIC ACID</strong></td>
<td><strong>Restricted benefit</strong></td>
<td>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent</td>
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<td><strong>OTHER BETA-LACTAM ANTIBACTERIALS</strong></td>
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<td>‡1</td>
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**CEPHALEXIN**

*Authority required (STREAMLINED)*

4243

Prophylaxis of urinary tract infection
## ANTIINFECTIVES FOR SYSTEMIC USE

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<th>Code</th>
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### CEPHALOTHIN

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

### CEPHAZOLIN

**Restricted benefit**

Cellulitis

**Note**

For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

### CEPHAZOLIN

**Restricted benefit**

Cellulitis

**Note**

For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

### CEPHAZOLIN

**Restricted benefit**

Cellulitis

**Note**

For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

### CEPHAZOLIN

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
### Second-generation cephalosporins

#### CEFACLOR

**Caution**

Serum sickness-like reactions have been reported with this drug, especially in children.

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**Third-generation cephalosporins**

- **CEFACLOFILM**
  - **Code**: B7.20
  - **Name**: Ceclor CD
  - **Restriction**: AS
  - **Manner of Administration and Form**: Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1
  - **Max. Qty (Packs)**: 1
  - **No. of Rpts**: ..
  - **Premium $**: 17.79
  - **Dispensed Price for Max. Qty $**: 21.30
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Ceclor CD, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 2002J
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1
  - **Max. Qty (Packs)**: 1
  - **No. of Rpts**: ..
  - **Premium $**: 19.80
  - **Dispensed Price for Max. Qty $**: 21.30
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 5499K
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1
  - **Max. Qty (Packs)**: 1
  - **No. of Rpts**: ..
  - **Premium $**: 19.80
  - **Dispensed Price for Max. Qty $**: 21.30
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 5052X
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: cefuroxime 250 mg tablet, 14
  - **Max. Qty (Packs)**: 1
  - **No. of Rpts**: 1
  - **Premium $**: 18.96
  - **Dispensed Price for Max. Qty $**: 20.11
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 8292K
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: cefuroxime 250 mg tablet, 14
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  - **No. of Rpts**: 1
  - **Premium $**: 18.96
  - **Dispensed Price for Max. Qty $**: 20.11
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 1758M
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: Powder for injection 1 g, 10
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  - **No. of Rpts**: ..
  - **Premium $**: 21.47
  - **Dispensed Price for Max. Qty $**: 22.62
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 1085D
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: cefotaxime 1 g injection, 1 x 1 g vial 10
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  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
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  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: Powder for injection 2 g, 10
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  - **Premium $**: 33.96
  - **Dispensed Price for Max. Qty $**: 35.11
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH

- **CEFURXIME AXETIL**
  - **Code**: 1086E
  - **Name**: Zinnat AS
  - **Restriction**: AS
  - **Manner of Administration and Form**: cefotaxime 2 g injection, 1 x 2 g vial 10
  - **Max. Qty (Packs)**: 10
  - **No. of Rpts**: ..
  - **Premium $**: 34.06
  - **Dispensed Price for Max. Qty $**: 35.21
  - **Maximum Recordable Value for Safety Net $**: 11.74
  - **Brand Name and Manufacturer**: Zinnat AS, Hospira Pty Limited HH
## ANTIIINFECTIVES FOR SYSTEMIC USE

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Fourth-generation cephalosporins

CEFEPIME
Authority required
Treatment of febrile neutropenia

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

8315P
CEFEPIME Powder for injection 1 g (as hydrochloride), 1

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*60.66

Brand Name and Manufacturer
Ceftriaxone ICP PP

8316Q
CEFEPIME Powder for injection 2 g (as hydrochloride), 1

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*109.36

Brand Name and Manufacturer
Ceftriaxone ICP PP

SULFONAMIDES AND TRIMETHOPRIM

Trimethoprim and derivatives

TRIMETHOPRIM
Authority required (STREAMLINED) 4243
Prophylaxis of urinary tract infection

2666H
trimethoprim 300 mg tablet, 7

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*10.68

Brand Name and Manufacturer
Alprim AF
Triprim QA

2922T
trimethoprim 300 mg tablet, 7

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*1.89

Brand Name and Manufacturer
Alprim AF
Triprim QA

Combinations of sulfonamides and trimethoprim, incl. derivatives

TRIMETHOPRIM + SULFAMETHOXAZOLE
Caution
There is an increased risk of severe adverse reactions with this combination in the elderly.

2951H
trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*3.90

Brand Name and Manufacturer
Resprim Forte AF
Bactrim DS RO

3390K
trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*3.90

Brand Name and Manufacturer
Resprim Forte AF
Bactrim DS RO

3103H
trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*4.25

Brand Name and Manufacturer
Resprim Forte AF
Bactrim DS RO

3391L
trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty $ Maximum Recordable Value for Safety Net $

*4.25

Brand Name and Manufacturer
Resprim Forte AF
Bactrim DS RO

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides
AZITHROMYCIN
Restricted benefit
## Antiinfectives for Systemic Use

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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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<td>Bordetella pertussis</td>
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ANTIIINFECTIVES FOR SYSTEMIC USE

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<td>2137.70</td>
<td>37.70</td>
<td></td>
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**Treatment Phase: Initial treatment**

**Clinical criteria:**

Patient must have cystic fibrosis,

AND

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result,

AND

Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

**Population criteria:**

Patient must be 6 years of age or older.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**TOBRAMYCIN**

**Authority required (STREAMLINED)**

4513

Proven Pseudomonas aeruginosa infection

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

Patient must have cystic fibrosis,

AND

Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules,

AND

Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

Patient must be 6 years of age or older.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**TOBRAMYCIN**

**Restricted benefit**

Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis
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**TOBRAMYCIN**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**QUINOLONE ANTIBACTERIALS**

**Fluoroquinolones**

**CIPROFLOXACIN**

**Authority required**

Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients

**Authority required**

Bacterial gastroenteritis in severely immunocompromised patients

**Authority required**

Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials

**Authority required**

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or periarticular infections of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials

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## ANTIINFECTIVES FOR SYSTEMIC USE

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## Antiinfectives for Systemic Use

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### Steroid Antibacterials

**FUSIDATE**

**Restricted benefit**

For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections.

**Imidazole Derivatives**

**METRONIDAZOLE**

**Restricted benefit**

- Treatment of anaerobic infections
- Prophylaxis to prevent infection

**Clinical criteria:**

- Patient must be undergoing large bowel surgery.

**Restricted benefit**

- Acute anaerobic sepsis

**Treatment criteria:**

- Must be treated in a hospital.

**Note**

- Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.
ANTIINFECTIVES FOR SYSTEMIC USE

### METRONIDAZOLE

**Restricted benefit**

Acute anaerobic sepsis

**Treatment criteria:**

Must be treated in a hospital.

**Note**

Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

**Nitrofuran derivatives**

**NITROFURANTOIN**

Caution

Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

**Other antibacterials**

**HEXAMINE HIPPURATE**

**ANTIMYCOTICS FOR SYSTEMIC USE**

**Triazole derivatives**

**FLUCONAZOLE**

Authority required (STREAMLINED)

3615

Treatment of cryptococcal meningitis

Authority required (STREAMLINED)

3616

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression

Authority required (STREAMLINED)

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3614

Treatment of oesophageal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3617

Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3618

Treatment of serious and life-threatening candida infections

**Note**

Shared Care Model:
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**FLUCONAZOLE**

**Authority required**

Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole

**Authority required**

Maintenance therapy in a patient with cryptococcal meningitis and immunosuppression unable to take a solid dose form of fluconazole

**Authority required**

Treatment of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole

**Note**

Shared Care Model:

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

**ITRACONAZOLE**

**Authority required (STREAMLINED)**

3607

Systemic aspergillosis

**Authority required (STREAMLINED)**

3608

Systemic sporotrichosis

**Authority required (STREAMLINED)**

3609

Systemic histoplasmosis

**Authority required (STREAMLINED)**

3610

Systemic candidiasis
ANTIINFECTIVES FOR SYSTEMIC USE

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**Note**

Shared Care Model:
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**POSACONAZOLE**

**Authority required**
Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy

**Authority required**
Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy

**Authority required**
Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:

1. Neutropenia

Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.

Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

2. Graft versus host disease (GVHD)

Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

**Note**
Application for an increased maximum quantity to allow for up to 1 month’s treatment and repeats sufficient for up to 6 months’ treatment may be authorised.

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

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**VORICONAZOLE**

**Authority required**
Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR

Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR

Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

**Note**

Application for an increased maximum quantity to allow for up to 1 month’s treatment and repeats sufficient for up to 6 months’ treatment may be authorised.

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

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Population criteria:**

Patient must be immunocompromised.

**Authority required**

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

The condition must be caused by Scedosporium species or Fusarium species.

**Authority required**

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

The condition must be caused by species not susceptible to fluconazole; OR The condition must be resistant to fluconazole; OR Patient must not tolerate fluconazole.

**Authority required**

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**Note**

Shared Care Model:

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

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Clinical criteria:
The condition must be caused by Scedosporium species or Fusarium species.

Authority required
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
The condition must be caused by species not susceptible to fluconazole; OR
The condition must be resistant to fluconazole; OR
Patient must not tolerate fluconazole.

Authority required
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

Note
Application for an increased maximum quantity to allow for up to 1 month’s treatment and repeats sufficient for up to 6 months’ treatment may be authorised.

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Hydrazides

ISONIAZID

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

1554T isoniazid 100 mg tablet, 100

DRUGS FOR TREATMENT OF LEPRO

Drugs for treatment of lepra

DAPSONE

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

1272Y dapsone 100 mg tablet, 100

8801F dapsone 25 mg tablet, 100

RIFAMPICIN

Restricted benefit
Prophylaxis of meningococcal disease in close contacts and carriers

Restricted benefit
Prophylactic treatment of contacts of patients with Haemophilus influenzae type B

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
## ANTIINFECTIVES FOR SYSTEMIC USE

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### RIFAMPICIN

**Authority required**

Leprosy in adults

### Note

Shared Care Model:

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## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

### ACICLOVIR

**Authority required (STREAMLINED)**

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment

### Note

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

### Note

For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

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### ACICLOVIR

**Authority required (STREAMLINED)**

3633

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpess. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

### Note

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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### ACICLOVIR
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**ACICLOVIR**

**Authority required (STREAMLINED)**

Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre)

**Authority required (STREAMLINED)**

Treatment of patients with herpes zoster within 72 hours of the onset of the rash

**Authority required (STREAMLINED)**

Herpes zoster ophthalmicus

**Note**

Aciclovir is effective only if commenced within 72 hours of onset of rash.

Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note**

No applications for repeats will be authorised.

**FAMCICLOVIR**

**Authority required (STREAMLINED)**

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**

Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**FAMCICLOVIR**

**Authority required (STREAMLINED)**

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**FAMCICLOVIR**

**Authority required (STREAMLINED)**

Treatment of patients with herpes zoster within 72 hours of the onset of the rash

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**FAMCICLOVIR**  
**Authority required (STREAMLINED)**  

3623  
Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**  
Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

3624  
Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological
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**Authority required (STRAIGHTENED)**

3627
Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

3628
Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 150 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

3629
Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

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**Authority required (STRAIGHTENED)**

3632
Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment

**Note**

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**Authority required (STRAIGHTENED)**

3623
Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**
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Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note**

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
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<td>8783G</td>
<td>diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes</td>
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<td>CS</td>
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**VACCINES**

**BACTERIAL VACCINES**

**Pneumococcal vaccines**

**PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES**

**Restricted benefit**

Splenectomised persons over 2 years of age

**Restricted benefit**

Persons with Hodgkin’s disease

**Restricted benefit**

Persons at high risk of pneumococcal infections

**Tetanus vaccines**

**DIPHTHERIA TOXOID + TETANUS TOXOID**

**Note**

For immunisation of adults and children aged greater than or equal to 8 years.

**ADT Booster**
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ANTINEOPLASTIC AGENTS

#### ALKYLATING AGENTS

**Nitrogen mustard analogues**

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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**CYCLOPHOSPHAMIDE**

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**MELPHALAN**

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#### Alkyl sulfonates

**BUSULFAN**

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<td>37.70</td>
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#### Nitrosoureas

**CARMUSTINE**

*Restricted benefit*

Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery

*Note*

Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

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#### Other alkylating agents

**TEMOZOLOMIDE**

*Authority required*

Recurrence of anaplastic astrocytoma following standard therapy

*Authority required*

Recurrence of glioblastoma multiforme following standard therapy

*Authority required*

Glioblastoma multiforme following radiotherapy

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</table>

**TEMOZOLOMIDE**

*Authority required*

Glioblastoma multiforme

**Treatment criteria:**

Patient must be undergoing concomitant radiotherapy.

**Note**

Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

**Note**

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

#### Folic acid analogues

**METHOTREXATE**

**Note**

For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

<table>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<td>METHOTREXATE Injection 50 mg in 2 mL, 1</td>
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<td>*19.71</td>
<td>20.86</td>
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<td>methotrexate 50 mg/2 mL injection, 5 x 2 mL vials</td>
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<td>19.69</td>
<td>20.84</td>
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<td>19.93</td>
<td>21.08</td>
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**METHOTREXATE Restricted benefit**

For patients requiring doses greater than 20 mg per week

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<td>51.58</td>
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#### Purine analogues

**FLUDARABINE**

**Authority required**

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:

(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and

(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

<table>
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<tr>
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#### Pyrimidine analogues

**CAPECITABINE**

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## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

**Vinca alkaloids and analogues**

**VINORELBINE**  
**Authority required**  
Advanced breast cancer  
**Clinical criteria:**  
Patient must have failed standard prior therapy, which includes an anthracycline.  
**Authority required**  
Locally advanced or metastatic non-small cell lung cancer

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**Podophyllotoxin derivatives**

**ETOPOSIDE**

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### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

**Anthracyclines and related substances**

**IDARUBICIN**  
**Restricted benefit**  
Acute myelogenous leukaemia

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### OTHER ANTINEOPLASTIC AGENTS

**Protein kinase inhibitors**

**DABRAFENIB**  
**Authority required**  
Unresectable Stage III or Stage IV malignant melanoma  
**Treatment Phase: Continuing treatment  
Clinical criteria:**  
The treatment must be the sole PBS-subsidised therapy for this condition, AND
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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**DABRAFENIB**

**Authority required**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

The condition must be positive for a BRAF V600 mutation,

AND

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal,

AND

Patient must have a WHO performance status of 2 or less.

**Note**

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note**

A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note**

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

**Note**

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

**Special Pricing Arrangements apply.**

**Note**

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

**Note**

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

**Special Pricing Arrangements apply.**

**DASATINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib.
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from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alpha therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

4. For imatinib mesylate, dasatinib and nilotinib

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**DASATINIB**

**Authority required**
Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.
Failure of an adequate trial of imatinib or nilotinib is defined as:
(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:
— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or
— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR
(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR
(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR
(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

**Note**

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

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Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. **Initial second line treatment**

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. **Initial third line treatment**

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.
From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.


Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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<td>2485T</td>
<td>dasatinib 70 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>6160.53</td>
<td>37.70</td>
<td>Sprycel BQ</td>
</tr>
</tbody>
</table>

**DASATINIB**

**Authority required**

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.
### ANTI NEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>6160.53</td>
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<td>Sprycel</td>
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</table>

### Authority required
Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

### Authority required
Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

### Note
Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

### Note
No applications for increased repeats will be authorised.

### ERLOTINIB

#### Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

The treatment must be as monotherapy,

AND

Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014,

AND

Patient must not have progressive disease.

**Population criteria:**

Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

### ERLOTINIB

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy,
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

### EVEROLIMUS

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,
- Patient must have a WHO performance status of 2 or less,
- The treatment must be the sole PBS-subsidised therapy for this condition.
Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- **Complete response (CR)**: Disappearance of all target lesions.
- **Partial response (PR)**: A 30% decrease in the sum of the longest diameter of target lesions.
- **Progressive disease (PD)**: A 20% increase in the sum of the longest diameter of target lesions.
- **Stable disease (SD)**: Small changes that do not meet above criteria.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression,
- The treatment must be as monotherapy.

Disease progression must be documented in the patient’s medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>10133H</td>
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<td>2846.70</td>
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<td>Afinitor</td>
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</table>

**EVEROLIMUS**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition,
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),
- The treatment must be the sole PBS-subsidised therapy for this condition,
- Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
**Stable disease (SD) is small changes that do not meet above criteria.**

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

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

**Note**
Special Pricing Arrangements apply.

**Authority required**
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug,

**AND**
Patient must not have disease progression,

**AND**
The treatment must be as monotherapy,

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

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

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

**Note**
Special Pricing Arrangements apply.

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**EVEROLIMUS**

**Authority required**
Tuberous sclerosis complex (TSC)

**Clinical criteria:**
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC,

**AND**
The treatment must be the sole PBS-subsidised therapy for this condition,

**AND**
Patient must not be a candidate for curative surgical resection.

**Note**
Special Pricing Arrangements apply.

**Authority required**
Tuberous sclerosis complex (TSC)

**Clinical criteria:**
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC,

**AND**
The treatment must be the sole PBS-subsidised therapy for this condition,

**AND**
Patient must have previously been treated with PBS-subsidised everolimus for this condition,

**AND**
Patient must have demonstrated a response to prior treatment.
### Antineoplastic and Immunomodulating Agents

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td><strong>Note</strong> Special Pricing Arrangements apply.</td>
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<td></td>
<td>Metastatic (Stage IV) breast cancer</td>
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<td><strong>Clinical criteria:</strong></td>
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<td></td>
<td>The condition must be hormone receptor positive,</td>
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<td></td>
<td>The condition must be human epidermal growth factor receptor 2 (HER2) negative,</td>
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<td>The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole,</td>
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<td>The treatment must be in combination with exemestane.</td>
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<td><strong>Population criteria:</strong></td>
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<td></td>
<td>Patient must not be pre-menopausal.</td>
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<td></td>
<td><strong>Note</strong> Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.</td>
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|       | **Authority required**                               |                  |             |           |                               |                                          |                               |
|       | Everolimus 10 mg tablet, 30                          | 1                | 5           | ..        | 5546.70                       | 37.70                                    | Afinitor NV                   |
|       | Everolimus 5 mg tablet, 30                           | 1                | 5           | ..        | 2846.70                       | 37.70                                    | Afinitor NV                   |

**EVEROLIMUS**

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been treated with PBS-subsidised everolimus for this condition,

AND

Patient must have demonstrated a response to prior treatment.

**Note** Special Pricing Arrangements apply.

|       | Everolimus 2.5 mg tablet, 30                          | 1                | 5           | ..        | 1483.50                        | 37.70                                    | Afinitor NV                   |
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<td>Iressa</td>
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<td>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</td>
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<td>Clinical criteria: The treatment must be as monotherapy,</td>
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<td></td>
<td>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,</td>
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<td>Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR</td>
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<td>Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,</td>
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<td>Patient must have a WHO performance status of 2 or less.</td>
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<td>Population criteria: Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.</td>
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<td>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</td>
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<td>Treatment Phase: Continuing treatment</td>
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<td>Clinical criteria: The treatment must be as monotherapy,</td>
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<td></td>
<td>Patient must have previously been issued with an authority prescription for this drug.</td>
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<td></td>
<td>Patient must not have progressive disease.</td>
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<tr>
<td>IMATINIB</td>
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<tr>
<td>8769M</td>
<td>IMATINIB Gastrointestinal stromal tumour</td>
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<td></td>
<td>Treatment Phase: Initial treatment</td>
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<td></td>
<td>Clinical criteria: The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),</td>
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<td></td>
<td>Patient must be at high risk of recurrence following complete surgical resection of primary GIST,</td>
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<td>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining,</td>
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<td>The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).</td>
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<td>Applications for authorisation of initial treatment must be in writing and must include:</td>
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<td>(1) a completed authority prescription form; and</td>
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<td></td>
<td>(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:</td>
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<td></td>
<td>(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and</td>
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<td></td>
<td>(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.</td>
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<td>High risk of recurrence is defined as:</td>
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<td>Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or</td>
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<tr>
<td></td>
<td>Primary GIST greater than 10 cm with any mitotic rate; or</td>
<td></td>
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</table>
Primary GIST with a mitotic count of greater than 10/50 HPF.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

Authority required
Gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

Clinical criteria:
The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),

AND
Patient must be at high risk of recurrence following complete surgical resection of primary GIST,

AND
The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy),

AND
Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

Note
Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

5443L
imatinib 100 mg tablet, 60
1
5
.. 1963.21 37.70
Glivec NV

5444M
imatinib 400 mg tablet, 30
1
5
.. 3779.71 37.70
Glivec NV

IMATINIB
Authority required
Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming
### IMATINIB

#### Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
4. a signed patient acknowledgement form

#### Authority required

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

#### Note

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

#### Note

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

#### Note

No applications for increased repeats will be authorised.

#### Authority required

#### Authority required
Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. demonstration of a response to treatment as evidenced by either:
   a. major cytogenetic response [see Note explaining requirements]; or
   b. a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

Note

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

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

   From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

   During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

   First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

   Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

   All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

   (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

   (ii) if at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

   During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

   Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response requirements.
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.

**Authority required**

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.

**Authority required**

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement.

**Authority required**

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia.

**Authority required**

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia.
Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | --- | ---
9115R | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 1963.21 | 37.70 | Glivec NV
9116T | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3779.71 | 37.70 | Glivec NV

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Authority required**

**IMATINIB**

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
(d) a signed patient acknowledgement

**Authority required**

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
(d) a signed patient acknowledgement

**Authority required**

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

- Medicare Australia
- Prior Written Approval of Specialised Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Note**

Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note**

No applications for increased repeats will be authorised.

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

1. Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
2. Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and
3. Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

- a completed authority prescription form; and
- a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Maximum dose: 800 mg per day.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
### IMATINIB

**Authority required**

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
- (d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
- (e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
- (f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
- (d) a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

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IMATINIB

Authority required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

1. there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and
2. the patient has previously failed an adequate trial of one or more of the following conventional therapies:
   - cytarabine;
   - etoposide;
   - hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
(e) details of the prior therapy trialled and the response; and
(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
(d) a statement that the disease has not progressed on imatinib therapy

Note

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;

Note

No applications for increased repeats will be authorised.
### IMATINIB

**Authority required**

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

1. there is confirmed evidence of the FIP1L1-PDGFRα fusion gene; and
2. the patient has previously failed an adequate trial of one or more of the following conventional therapies:
   - corticosteroids;
   - hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
3. a copy of the pathology report confirming the presence of the FIP1L1-PDGFRα fusion gene; and
4. a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
5. details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
6. details of prior treatment trialled and the response; and
7. a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRα fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
3. a copy of the full blood examination report which demonstrates a complete haematological response; and
4. a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.
LAPATINIB
Authority required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with a taxane, for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form;
(b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);
(c) date of last treatment with a taxane and total number of cycles;
(d) a signed patient acknowledgment;
(e) dates of treatment with trastuzumab; and
(f) date of demonstration of progression whilst on treatment with trastuzumab

Authority required

Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a statement from the prescribing doctor that the disease has not progressed

Note

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

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

Note

Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses.

If treatment with a taxane is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9148L lapatinib 250 mg tablet, 70 2 2 .. *3387.80 37.70 Tykerb

NILOTINIB
Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
(4) a signed patient acknowledgement form

Authority required
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

NILOTINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:
   — failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or
   — failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
   — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment
From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment
Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.
Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.


Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level at greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

9171Q NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120

PAZOPANIB

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

Patient must require dose adjustment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

10054E pazopanib 200 mg tablet, 30

10052C pazopanib 400 mg tablet, 30

PAZOPANIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

Patient must require dose adjustment,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Note

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.
Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Response Evaluation Criteria In Solid Tumours (RECIST)** is defined as follows:

- **Complete response (CR)** is disappearance of all target lesions.
- **Partial response (PR)** is a 30% decrease in the sum of the longest diameter of target lesions.
- **Progressive disease (PD)** is a 20% increase in the sum of the longest diameter of target lesions.
- **Stable disease (SD)** is small changes that do not meet above criteria.

**Special Pricing Arrangements** apply.

### PAZOPANIB

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less,
- Patient must have received prior chemotherapy treatment including an anthracycline,
- Patient must not have received prior treatment with an angiogenesis inhibitor,
- The treatment must be the sole PBS-subsidised therapy for this condition.
- The authority application must be made in writing.

**Note**

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

**Note**

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

**Special Pricing Arrangements** apply.
Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

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PAZOPANIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

Note

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

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PAZOPANIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months
**Pazopanib**

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**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib,
- AND
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),
- AND
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

- Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.
- Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have been receiving treatment with pazopanib prior to 1 October 2012,
- AND
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

Special Pricing Arrangements apply.

**SORAFENIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,
- AND
- Patient must have a WHO performance status of 2 or less,
- AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

- Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

- A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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</table>

**SORAFENIB**

### Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug for this condition,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

### Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

### Note

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

### Note

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

### Note

Special Pricing Arrangements apply.

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</tbody>
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**SORAFENIB**

### Authority required (STREAMLINED)

4230

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

Treatment Phase: Initial

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have a WHO performance status of 2 or less,

AND

Patient must have Child Pugh class A.

### Authority required (STREAMLINED)

4234

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

Treatment Phase: Continuing

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been treated with PBS-subsidised sorafenib,
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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</tr>
</tbody>
</table>

**SUNITINIB**

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression,

**AND**

- The treatment must be as monotherapy.

Disease progression must be documented in the patient’s medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

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**SUNITINIB**

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug,

**AND**

- Patient must not have disease progression,

**AND**

- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**Note**
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**SUNITINIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,
- Patient must have a WHO performance status of 2 or less,
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**Note**

Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note**

Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

9417P    | sunitinib 12.5 mg capsule, 28                       | 1               | 1           | ..       | 1834.54                       | 37.70                           | Sutent PF                      |
9418Q    | sunitinib 25 mg capsule, 28                         | 1               | 1           | ..       | 3522.10                       | 37.70                           | Sutent PF                      |
9419R    | sunitinib 50 mg capsule, 28                         | 1               | 1           | ..       | 6897.78                       | 37.70                           | Sutent PF                      |

**SUNITINIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Treatment Phase:** Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for sunitinib,
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note**

Patients who have progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.
Response Evaluation Criteria in Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

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Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note**
Special Pricing Arrangements apply.

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**SUNITINIB**

**Authority required**

Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

**Authority required**

Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

Patients who have progressive disease on sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe sunitinib malate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

**Note**
Special Pricing Arrangements apply.

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**Other antineoplastic agents**

HYDROXYUREA
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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### ENDOCRINE THERAPY

## HORMONES AND RELATED AGENTS

### Progestogens

**MEDROXYPROGESTERONE**

**Restricted benefit**

Hormone-dependent breast cancer

**Restricted benefit**

Endometrial cancer

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**MEDROXYPROGESTERONE**

**Restricted benefit**

Hormone-dependent advanced breast cancer

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**MEGESTROL**

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### Gonadotropin releasing hormone analogues

**GOSERELIN**

**Authority required (STREAMLINED)**

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**GOSERELIN**

**Authority required**

Locally advanced (stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Authority required**

Locally advanced (Stage III) or metastatic (Stage IV) breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive.

**Authority required**

Endometriosis

**Clinical criteria:**

The condition must be visually proven,

**AND**

The treatment must be for the short-term (up to 6 months).

**Note**

Only 1 course of not more than 6 months' therapy will be authorised.

**Authority required**

Breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive,

**AND**

The treatment must be an alternative to adjuvant chemotherapy.
### Goserelin (G) & Bicalutamide

**Authority required (STREAMLINED)**

**Code**
- 9065D: goserelin 10.8 mg implant [1 implant] 
  & bicalutamide 50 mg tablet [28 tablets], 1 pack
- 9066E: goserelin 10.8 mg implant [1 implant] 
  & bicalutamide 50 mg tablet [84 tablets], 1 pack
- 9064C: goserelin 3.6 mg implant [1 implant] 
  & bicalutamide 50 mg tablet [28 tablets], 1 pack

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

### Leuprolrelin

**Authority required (STREAMLINED)**

**Code**
- 8708H: leuprorelin acetate 22.5 mg injection: modified release [1 syringe] 
  & inert substance diluent [1 syringe], 1 pack
- 8876E: leuprorelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] 
  & inert substance diluent [1 x 2 mL syringe], 1 pack
- 8709J: leuprorelin acetate 30 mg injection: modified release [1 syringe] 
  & inert substance diluent [1 syringe], 1 pack
- 8877F: leuprorelin acetate 30 mg injection: modified release [1 x 30 mg syringe] 
  & inert substance diluent [1 x 2 mL syringe], 1 pack
- 8859G: leuprorelin acetate 45 mg injection: modified release [1 syringe] 
  & inert substance diluent [1 syringe], 1 pack
- 8707G: leuprorelin acetate 7.5 mg injection: modified release [1 syringe] 
  & inert substance diluent [1 syringe], 1 pack
- 8875D: leuprorelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] 
  & inert substance diluent [1 x 2 mL syringe], 1 pack

### Triptorelin

**Authority required (STREAMLINED)**

**Code**
- 9379P: triptorelin 11.25 mg injection [1 x 11.25 mg vial] 
  & inert substance diluent [1 x 2 mL ampoule], 1 pack
- 5297T: triptorelin 22.5 mg injection [1 x 22.5 mg vial] 
  & inert substance diluent [1 x 2 mL ampoule], 1 pack
- 9378N: triptorelin 3.75 mg injection [1 x 3.75 mg vial] 
  & inert substance diluent [1 x 2 mL ampoule], 1 pack

### Hormone Antagonists and Related Agents

#### Anti-estrogens

**Tamoxifen**

Restricted benefit
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<td><strong>Note</strong> This drug is not PBS-subsidised for primary prevention of breast cancer.</td>
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**ENZALUTAMIDE**

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

The treatment must not be used in combination with chemotherapy,

**AND**

Patient must have failed treatment with docetaxel due to resistance or intolerance; OR

Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel,

**AND**

Patient must have a WHO performance status of 2 or less,

**AND**

Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**AND**

Patient must not have received prior treatment with abiraterone; OR

Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

**Note**

Special Pricing Arrangements apply.

**Note**

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

**Note**

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

**FLUTAMIDE**

**Authority required (STREAMLINED)**

3674

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Shared Care Model:

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

**NILUTAMIDE**
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<th>Brand Name and Manufacturer</th>
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</table>

**Aromatase inhibitors**

#### ANASTROZOLE

**Restricted benefit**

Breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive.

**Population criteria:**

Patient must not be pre-menopausal.

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

**Notes**

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Shared Care Model:**

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

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#### EXEMESTANE

**Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive,

**AND**

The condition must be human epidermal growth factor receptor 2 (HER2) negative.
**EXEMESTANE**

**Restricted benefit**

Advanced breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive,

AND

The condition must have progressed following treatment with tamoxifen.

**Population criteria:**

Patient must not be pre-menopausal.

**LETROZOLE**

**Restricted benefit**

Breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive.

**Population criteria:**

Patient must not be pre-menopausal.

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<th>Code</th>
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<td>a Exemestane Sandoz Sz</td>
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</table>
### Restricted benefit

**Early breast cancer**

**Clinical criteria:**

- The condition must be hormone receptor positive,
- The treatment must be for extended adjuvant treatment of the condition commencing within 6 months of ceasing treatment with tamoxifen.

**Population criteria:**

- Patient must not be pre-menopausal.

**Note**

- This drug is not PBS-subsidised for primary prevention of breast cancer.
- This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Shared Care Model:**

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

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<th>Maximum Recordable Value for Safety Net $</th>
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### Other hormone antagonists and related agents

**ABIRATERONE**

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with prednisone or prednisolone,
- The treatment must not be used in combination with chemotherapy,
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel,
- Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone,
- Patient must not have received prior treatment with enzalutamide; OR
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2698B</td>
<td>abiraterone acetate 250 mg tablet, 120</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>3600.24</td>
<td>37.70</td>
<td>Zytiga JC</td>
</tr>
<tr>
<td></td>
<td><strong>Note</strong></td>
<td></td>
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<tr>
<td></td>
<td>Special Pricing Arrangements apply.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2785N</td>
<td>degarelix 120 mg injection [2 x 120 mg vials] (&amp;) inert substance diluent [2 syringes], 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>439.06</td>
<td>37.70</td>
<td>Firmagon 120mg FP</td>
</tr>
<tr>
<td>2784M</td>
<td>degarelix 80 mg injection [1 x 80 mg vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>420.54</td>
<td>37.70</td>
<td>Firmagon 80mg FP</td>
</tr>
</tbody>
</table>

**IMMUNOSTIMULANTS**

**Interferons**

INTERFERON ALFA-2A

**Authority required**

Hairy cell leukaemia

**Authority required**

Myeloproliferative disease with excessive thrombocytosis

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

8180M interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe 15 4 .. *506.56 37.70 Roferon-A RO

8181N interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe 15 5 .. *506.56 37.70 Roferon-A RO

8182P interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *265.06 37.70 Roferon-A RO

8183Q interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *345.06 37.70 Roferon-A RO

8184R interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *506.46 37.70 Roferon-A RO

**INTERFERON ALFA-2A**

**Authority required**

Low grade non-Hodgkin’s lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

8181N interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe 15 5 .. *506.56 37.70 Roferon-A RO

8182P interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *265.06 37.70 Roferon-A RO

8183Q interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *345.06 37.70 Roferon-A RO

8184R interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe 5 5 .. *506.46 37.70 Roferon-A RO

**INTERFERON ALFA-2A**

**Authority required**

Myeloproliferative disease with excessive thrombocytosis

**Caution**

Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

**Note**

Special Pricing Arrangements apply.

**2698B**

abiraterone acetate 250 mg tablet, 120 1 2 .. 3600.24 37.70 Zytiga JC

**DEGARELIX**

**Authority required (STREAMLINED)**

3229

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

2785N degarelix 120 mg injection [2 x 120 mg vials] (&) inert substance diluent [2 syringes], 1 pack 1 .. .. 439.06 37.70 Firmagon 120mg FP

**DEGARELIX**

**Authority required (STREAMLINED)**

3229

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

2784M degarelix 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 syringe], 1 pack 1 5 .. 420.54 37.70 Firmagon 80mg FP
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>8551C</td>
<td>interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>5</td>
<td>4</td>
<td>..</td>
<td>265.06</td>
<td>37.70</td>
<td>Roferon-A RO</td>
</tr>
<tr>
<td>8552D</td>
<td>interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>5</td>
<td>4</td>
<td>..</td>
<td>345.06</td>
<td>37.70</td>
<td>Roferon-A RO</td>
</tr>
<tr>
<td>8553E</td>
<td>interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>5</td>
<td>4</td>
<td>..</td>
<td>506.46</td>
<td>37.70</td>
<td>Roferon-A RO</td>
</tr>
</tbody>
</table>

**INTERFERON ALFA-2B**

**Authority required**

Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy

**Authority required**

Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8348J</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>606.37</td>
<td>37.70</td>
<td>Intron A Redipen MK</td>
</tr>
<tr>
<td>8476D</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>1006.09</td>
<td>37.70</td>
<td>Intron A Redipen MK</td>
</tr>
</tbody>
</table>

**INTERFERON ALFA-2B**

**Authority required**

Hairy cell leukaemia

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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</thead>
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<tr>
<td>8572E</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>3</td>
<td>4</td>
<td>..</td>
<td>606.37</td>
<td>37.70</td>
<td>Intron A Redipen MK</td>
</tr>
</tbody>
</table>

**INTERFERON BETA-1A**

**Authority required**

Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

**Authority required**

Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| INTERFERON BETA-1B  
Authority required  
Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule  
Authority required  
Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule |

| 8101J | interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack | 1 | 5 | .. | 1001.15 | 37.70 | Betaferon BN |

| PEGINTERFERON BETA-1A  
Authority required  
Multiple sclerosis  
Treatment Phase: Initial treatment  
Clinical criteria:  
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR  
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND  
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND  
Patient must be ambulatory (without assistance or support).  
Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.  
Note  
No increase in the maximum quantity or number of units may be authorised.  
Note  
No increase in the maximum number of repeats may be authorised. |

| 10212L | peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices | 1 | 4 | .. | 1057.11 | 37.70 | Plegridy BD |
| 10218T | peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack | 1 | .. | .. | 1057.11 | 37.70 | Plegridy BD |

| PEGINTERFERON BETA-1A  
Authority required  
Multiple sclerosis  
Treatment Phase: Continuing treatment  
Clinical criteria:  
Patient must have previously been issued with an authority prescription for this drug.  
AND  
Patient must not show continuing progression of disability while on treatment with this drug.  
AND  
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.  
Note  
No increase in the maximum quantity or number of units may be authorised. |
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Note</strong></td>
<td>No increase in the maximum number of repeats may be authorised.</td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>10220X</td>
<td>peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices</td>
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<td>5</td>
<td>1057.11</td>
<td>37.70</td>
<td></td>
<td>Plegridy BD</td>
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</tbody>
</table>

**Other immunostimulants**

**BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN**

**Restricted benefit**

Treatment of carcinoma in situ of the urinary bladder

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1140B</td>
<td>Bacillus Calmette and Guerin- Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (6x inert substance diluent [1 x 3 mL vial], 1 pack</td>
<td>3</td>
<td>1</td>
<td>&quot;460.21</td>
<td>37.70</td>
<td></td>
<td>ImmuCyst SW</td>
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</tbody>
</table>

**BACILLUS CALMETTE AND GUERIN-TICE STRAIN**

**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1131M</td>
<td>Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials</td>
<td>1</td>
<td>1</td>
<td>556.73</td>
<td>37.70</td>
<td></td>
<td>OncoTICE MK</td>
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</tbody>
</table>

**GLATIRAMER ACETATE**

**Authority required**

Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

**Authority required**

Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

<table>
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<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8726G</td>
<td>glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes</td>
<td>1</td>
<td>5</td>
<td>1092.99</td>
<td>37.70</td>
<td></td>
<td>Copaxone CS</td>
</tr>
</tbody>
</table>

### IMMUNOSUPPRESSANTS

**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6
months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription forms; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment without a loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

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

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised biDMARD antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs
and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the
time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept patients:**

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined on the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

**AND**

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

**AND**

Patient must not receive more than 16 weeks of treatment under this restriction,

**AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription forms; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.
Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

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

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

Special Pricing Arrangements apply.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised treatment was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may try an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the
subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

1220F abatacept 125 mg/mL injection, 4 x 1 mL syringes

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**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

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

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

Special Pricing Arrangements apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying
antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised treatment was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to take any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Exception as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Pack(s))</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>MaximumRecordableValueforSafetyNet$</th>
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## EVEROLIMUS

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

## FINGOLIMOD

**Authority required**

Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule.

**Authority required**

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.

**Note**

Special Pricing Arrangements apply.

## LEFLUNOMIDE

**Authority required (STREAMLINED)**

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

**Caution**

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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<thead>
<tr>
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### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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#### LEFLUNOMIDE

- **8374R**
  - Leflunomide 10 mg tablet, 30
  - 1 5 .. 48.94 37.70
  - a APO-Leflunomide
  - a Arabloc
  - a Arava
  - a Leflunomide AN
  - a Leflunomide-GA
  - a Leflunomide GH
  - a Leflunomide Sandoz
  - a Lunava 10
  - SW
  - TX

- **8375T**
  - Leflunomide 20 mg tablet, 30
  - 1 5 .. 69.85 37.70
  - a APO-Leflunomide
  - a Arabloc
  - a Arava
  - a Leflunomide AN
  - a Leflunomide-GA
  - a Leflunomide GH
  - a Leflunomide Sandoz
  - a Lunava 20
  - SW
  - ZP

#### MYCOPHENOLATE

- **2150E**
  - Mycophenolate 180 mg tablet: enteric, 120 tablets
  - 1 5 .. 135.45 37.70
  - Myfortic
  - NV

- **2193K**
  - Mycophenolate 360 mg tablet: enteric, 120 tablets
  - 1 5 .. 258.73 37.70
  - Myfortic
  - NV

#### MYCOPHENOLATE

- **8652J**
  - Mycophenolate 180 mg tablet: enteric, 120 tablets
  - 1 3 .. 135.45 37.70
  - Myfortic
  - NV

- **8653K**
  - Mycophenolate 360 mg tablet: enteric, 120 tablets
  - 1 3 .. 258.73 37.70
  - Myfortic
  - NV
### MYCOPHENOLATE

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

**Note**

For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

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<th>Code</th>
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**SIROLIMUS**

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

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<th>Code</th>
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</tbody>
</table>

**TERIFLUNOMIDE**

**Authority required**

Multiple sclerosis
Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND

Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Authority required
Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Caution

Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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

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

Note
Special Pricing Arrangements apply.

teriflunomide 14 mg tablet, 28
1
5
.. 1847.26
37.70
Aubagio

Tumor necrosis factor alpha (TNF-) inhibitors

ADALIMUMAB

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the
<table>
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<tr>
<th>Code</th>
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</thead>
</table>

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) had a break in therapy of more than 24 months.

With respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has

Patient must have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<th>Code</th>
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**AND**

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a
(iv) a patient wishes to re-commence treatment with a specific bDMARD following details are under ‘Swapping therapy’ below; or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further
Where a response assessment is not submitted to the Depar
assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment with that agent (Initial 2).

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD, or respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient who was receiving PBS-subsidised bDMARD therapy immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in PBS-subsidised therapy with

There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised bDMARD treatment with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any
time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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<td>1774.70</td>
<td>37.70</td>
<td>Humira</td>
</tr>
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</table>

**ADALIMUMAB**

**Authority required**

Severe active idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
Antineoplastic and Immunomodulating Agents

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1);
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatnent criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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**ADALIMUMAB**

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

**Authority required**

Initial 2
Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF COMPLEX REFRAC'TORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a

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**Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.**

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

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**Note**

TREATMENT OF COMPLEX REFRAC'TORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under infliximab will be authorised under this criterion.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion (b) a completed Fistulising Crohn Disease PBS Authority Application - (a) a completed authority prescription form; and

Applications for authorisation must be made in writing and must include:

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

No applications for increased maximum quantities and/or repeats will be authorised.

## Note

No applications for increased maximum quantities and/or repeats will be authorised.

### ADALIMUMAB

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to...
have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.
A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist within the same treatment cycle.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment.

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy

(b) Initial treatment.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

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

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

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<td>..</td>
<td>1774.70</td>
<td>37.70</td>
<td>Humira VE</td>
</tr>
<tr>
<td>8964T</td>
<td>adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes</td>
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<td>5</td>
<td>..</td>
<td>1774.70</td>
<td>37.70</td>
<td>Humira VE</td>
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</tbody>
</table>

**ADALIMUMAB**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the
The application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.
Special Pricing Arrangements apply

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

A patient whose most recent course of PBS-subsidised treatment failed to respond to therapy, including at least 12 months of treatment with PBS-subsidised therapy, failure to respond to at least 1 drug before PBS-subsidised therapy, and no response to one course of PBS-subsidised treatment.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

Notes:

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

A patient whose most recent course of PBS-subsidised therapy failed to respond to therapy, including at least 12 months of treatment with PBS-subsidised therapy, failure to respond to at least 1 drug before PBS-subsidised therapy, and no response to one course of PBS-subsidised treatment.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

Notes:

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two
prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis
<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispersed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)**

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

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

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

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
1. **Code**

2. **Name, Restriction, Manner of Administration and Form**

3. **Max. Qty (Packs)**

4. **No. of Rpts**

5. **Premium $**

6. **Dispensed Price for Max. Qty $**

7. **Maximum Recordable Value for Safety Net $**

8. **Brand Name and Manufacturer**

### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

#### Note

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).  

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:**

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

**Rituximab patients:**

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints.

Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment;

AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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ADALIMUMAB

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis,
AND
Patient must have demonstrated an adequate response to treatment with this drug,
AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,
AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,
AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

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

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with a bDMARD was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further

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It is recommended that a patient be reviewed in the month prior to completing their current course of treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment.

Abatacept patients:

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent (Initial 1). Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date the course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to respond to rituximab and who qualify and wish to trial a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course...
of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**ADALIMUMAB**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,
Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

**Note**
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

**AND**
Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

**AND**
Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

**AND**
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,
AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a
biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

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

**Note**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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<td>37.70</td>
<td>Humira</td>
</tr>
</tbody>
</table>

**ADALIMUMAB**
Severe psoriatic arthritis

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug.

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes,
patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

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

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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<td>VE</td>
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ADALIMUMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal,

the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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

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

Authority required
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,
AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,
AND
Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,
AND
Patient must be eligible to receive further bDMARD therapy.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol,
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to swap therapy.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient who has received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Following an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD [further details]. Prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

- Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

- Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**ADALIMUMAB**

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis,

AND

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

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

Note

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

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVEankylosing spondylitis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

**Ankylosing spondylitis**

**Treatment Phase: Continuing treatment – balance of supply**

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

**AND**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

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

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

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

9104E adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 1 5 .. 1774.70 37.70 Humira VE

9078T adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 1 5 .. 1774.70 37.70 Humira VE

ADALIMUMAB
Authority required
Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.
All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient’s condition; and
It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult consultant physicians [general medicine specialising in gastroenterology (code 81)].

If intolerance to treatment develops during the relevant period of use, which is of a severity nec—

provide details at the time of application.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult consultant physicians [general medicine specialising in gastroenterology (code 81)].

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month follow—

ing cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy); and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare
It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient who:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has met the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist treatment within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To determine eligibility for continuing treatment, the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with severe small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has met the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has not failed to respond to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or...
A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. (iii) date of the most recent clinical assessment; and (a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; AND/OR (b) have evidence of active intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR (c) be assessed clinically as being in a high faecal output state; AND/OR (d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient’s condition, if relevant; and (iii) date of the most recent clinical assessment; and (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion. Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Note Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to commence a further course of treatment within the same treatment cycle.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that

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(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index [CDAI] Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

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### ADALIMUMAB

**Authority required**

**Initial 3 (grandfather)**

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not...
meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:
   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
   (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
   (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient’s assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks of treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:
   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
   (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
   (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient’s condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient’s assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.
The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients who are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alpha antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for
From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 2 weeks prior to the course that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9191R

adalimumab 40 mg/0.8 mL injection, 2 x 1 5 .. 1774.70 37.70 Humira VE

0.8 mL cartridges
ADALIMUMAB

Authority required

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgments.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of the initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but not longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

**Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]**

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications or for treatment that would otherwise extend the initial treatment period beyond 16 weeks. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous...
treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle. Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

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<td>37.70</td>
<td>Humira</td>
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ADALIMUMAB

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare
This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline values; or (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that biological agent.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010. A patient who received PBS-subsidised biological agent treatment for severe chronic plaque psoriasis after 1 March 2010 is considered to be in their first Cycle as of 1 March 2010. Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010. There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment if they meet the response criteria for each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.
treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

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CERTOLIZUMAB PEGOL

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst
completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note**
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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

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

**Authority required**
Ankylosing spondylitis

**Treatment Phase:** Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,
Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

While a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment,

AND
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

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

**Note**

No increase in the maximum number of repeats may be authorised.
A patient must be assessed for response to any course of initial PBS-
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle, provided they have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle.
cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required
Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

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

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

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

10137M certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes 1 5 .. 1708.98 37.70 Cimzia UC

CERTOLIZUMAB PEGOL

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)
### Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

### Population criteria:

Patient must be an adult.

### Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

#### Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

#### Note

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

#### Note

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

#### Note

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

#### Note
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Special Pricing Arrangements apply.

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

- either of the following:

  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Special Pricing Arrangements apply.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below).

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment.

AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

Note
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

**Note**
Special Pricing Arrangements apply.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,
AND
Patient must have been receiving treatment with certolizumab pegol for this condition prior to 1 April 2015,
AND
Patient must be receiving treatment with certolizumab pegol at the time of application,
AND
Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol,
AND
Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.
A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note**
Special Pricing Arrangements apply.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Applications for initial PBS-subsidised treatment for non-grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing therapy as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS subsidised biological agent more than once. Therefore patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below]. The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing...
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent and Form. Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below).

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.
Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients will be deemed to have failed to respond to treatment with that drug providing they have demonstrated an adequate response to treatment.

### Authority required

**Severe psoriatic arthritis**

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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<td>5</td>
<td>1708.98</td>
<td>37.70</td>
<td>Cimzia</td>
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**CERTOLIZUMAB PEGOL**

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

AND

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times.,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible...
to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the initial authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP level must be provided to determine response. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP level measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.
Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab. 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count).
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen.

AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. AND

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. OR

Treatment criteria:

Agent.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
ETANERCEPT

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLACAE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised etanercept and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be submitted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have lesions present for at least 6 months from the time of initial diagnosis,

AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months,

AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment. There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.
### Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment or Re-treatment (Whole body) - balance of first supply

**Clinical criteria:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND**

Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a dermatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

1. Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

2. Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:
Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate.

AND

Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis.

AND

Patient must have demonstrated an adequate response to treatment.

AND

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:

Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient’s condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient’s response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note

In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Assessment submitted with the first authority application for etanercept.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.
The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

**Treatment Phase: Re-treatment (Whole body)**

**Clinical criteria:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have a documented history of severe chronic plaque psoriasis of the whole body,

AND

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,

AND

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patient’s PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

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

**Note**

No increase in the maximum number of repeats may be authorised.
This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. The PASI assessment must be conducted after at least 12 weeks of treatment.

Treatment Phase: Initial treatment (Face, hand, foot)

Severe chronic plaque psoriasis

Must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis.

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent course of etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate.

AND

Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months,

AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:
Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:
Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
   (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:
   (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition
   (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
   (iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note
Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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

**Authority required**

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

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

1. Application for approval for initial treatment.
2. Applications for approval for re-treatment.
3. Applications for approval for completion of a course

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patient's PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

Applications for re-treatment should be made in the following situations:

1. Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to the Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

4. Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

5. Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

**Clinical criteria:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate.
Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Applications for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

Applications for re-treatment should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Applications for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

Applications for further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

Note

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

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Applications for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

Applications for further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.
The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

Clinical criteria:
The treatment must be as systemic monotherapy; OR
The treatment must be in combination with methotrexate,

AND
Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis,

AND
Patient must have demonstrated an adequate response to treatment,

AND
Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:
Must be treated by a dermatologist.
An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the PASI symptom scores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient’s condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient’s response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note
It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note
In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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

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

Note
Special Pricing Arrangements apply.

**Authority required**

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

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

i. a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

ii. a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

i. all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

ii. the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.
A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

**Clinical criteria:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot,

AND

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,

AND

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.
ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND...
either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**
Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Clinical criteria:**
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

A patient who was receiving PBS-subsidised bDMARD therapy was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle.

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

1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

3447K  ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 1 3 .. 1774.71 37.70 Enbrel PF

3446J  ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 1 3 .. 1774.71 37.70 Enbrel PF

3445H  etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack 2 3 .. *1774.70 37.70 Enbrel PF

**ETANERCEPT**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND
Patient must have demonstrated an adequate response to treatment with etanercept.

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle.

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application – Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are
assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**ETANERCEPT**

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note**

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note**

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

**Note**

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

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

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

**Note**

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING Spondylitis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised therapy of at least 5 years, must requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may wish to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing). Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment of each initial treatment application are to be used for all subsequent bDMARD treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent bDMARD treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis.

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.
## ETANERCEPT

### Authority required

Ankylosing spondylitis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last

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prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing...
bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis,

AND

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

- Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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</table>
ETANERCEPT
Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is
Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
Patient must have a documented history of severe active psoriatic arthritis,

AND
Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND
Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.
Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.
An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/ or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

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

**Note**

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological
agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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**ETANERCEPT**

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

AND
Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND
Patient must demonstrate, at the time of application, an adequate response to treatment with this drug.

AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment.
with the initial treatment course.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

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

**Note**

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

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

Note

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

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

9458T

ETANERCEPT Injection 50 mg in 1 mL

double use auto-injector, 4, 1

1 5 .. 1774.71 37.70 Enbrel PF

9088H

ETANERCEPT Injections 50 mg in 1 mL

double use pre-filled syringes, 4, 1

1 5 .. 1774.71 37.70 Enbrel PF

9036N

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

2 5 .. *1774.70 37.70 Enbrel PF

ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

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

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

Special Pricing Arrangements apply.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services in the following circumstances:

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient (b) Continuing treatment.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uni

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed to respond to treatment with that bDMARD.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of
active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis,

AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND
Patient must not receive more than 16 weeks of treatment under this restriction.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of Initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted.
with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

9459W ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

1 3 .. 1774.71 37.70 Enbrel PF

9089J ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

1 3 .. 1774.71 37.70 Enbrel PF

8637N etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

2 3 .. *1774.70 37.70 Enbrel PF

ETANERCEPT
Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease-modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
It is recommended that a patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD agent.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Writte: Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

9460X  ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1
0909K  ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1
8638P  etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

ETANERCEPT

Authority required
Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.
A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.
not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 0.4 mg per kg per day for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

**Initial or re-Treatment [Initial 2. Face, hand, foot (Received prior biological agent under PBS)]**

- Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
  - (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
  - (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
  - (c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first...
There is no limitation on the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010. There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands, and feet.

1. Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.


When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.


Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

4. Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must demonstrate a response to treatment for the purposes of all continuing treatment applications.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>Enbrel</td>
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ETANERCEPT
Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must
cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between
the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new
Cycle.

Authority required
Continuing treatment (face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or
sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the
first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an
initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare
Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet
and face, hand, foot area diagrams along with the date of the
assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a
maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5
p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment
that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment
must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response
assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to
treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call
Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment
course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must
cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between
the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new
Cycle.

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab,
etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’
appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept,
infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab,
etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’
appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept,
infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when
swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

 Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Special Pricing Arrangements apply.

**GOLIMUMAB**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for...
The following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2...
infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed to receive treatment with that bDMARD.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response
According to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of
movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of treatment under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of Initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

 Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are reviewed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to wait any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements at any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

3426H
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe
1 3 .. 1777.63 37.70 Simponi JC

3427J
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe
1 3 .. 1777.63 37.70 Simponi JC

**GOLIMUMAB**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
### ANTI NEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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An adequate response to treatment is defined as:

- An ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. A completed authority prescription form and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs
and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Note

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment.

**AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

3428K golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe 1 5 .. 1777.63 37.70 Simponi JC

3429L golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe 1 5 .. 1777.63 37.70 Simponi JC

GOLIMUMAB
Severe psoriatic arthritis

Clinical criteria:
Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</table>

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

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

**Authority required**
Severe psoriatic arthritis

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

or the following:

1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to try a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint count are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

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

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

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

### GOLIMUMAB

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
### TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<td><strong>Note</strong> Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.</td>
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<td><strong>Note</strong> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>. Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs. Reply Paid 9826. GPO Box 9826. HOBART TAS 7001</td>
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<td>(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and</td>
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<td>(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and</td>
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<td>(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).</td>
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Patients who wish to trial a second or subsequent biological agent must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

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

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**3432P**
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

- Max. Qty (Packs): 1
- No. of Rpts: 5
- Dispensed Price for Max. Qty: 1777.63
- Premium $: 37.70
- Brand Name and Manufacturer: Simponi JC

**GOLIMUMAB**

**Authority required**
Active ankylosing spondylitis

**Treatment Phase:** Initial 1 (new patients)

**Clinical criteria:**
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.
The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.
Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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

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

Authority required
Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment
cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

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

**Note**

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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GOLIMUMAB

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

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

**Note**

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

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**USTEKINUMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with

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**Interleukin inhibitors**

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**USTEKINUMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with
phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to their most recent course of PBS-subsidised ustekinumab treatment. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is
not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed following the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

1. Phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
2. Methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
3. Cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
4. Acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

1. at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
2. the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

1. The completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
2. Details of previous phototherapy and systemic drug therapy (dosage [where applicable], date of commencement and duration of therapy); and
3. The signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to

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treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.
From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within...
the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

Note
Special Pricing Arrangements apply.

9304Q

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USTEKINUMAB

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to treatment with ustekinumab.

An adequate response to ustekinumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACED PSORIASIS
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
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The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they respond to a therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under (4) Swapping therapy below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

Note
Special Pricing Arrangements apply.

9305R ustekinumab 45 mg/0.5 mL injection, 1 1 1 ... 4601.76 37.70 Stelara JC

Calcineurin inhibitors

**CYCLOSPORIN**

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe psoriatic arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate. Therapy must remain under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient. The name of the rheumatologist or specialised unit must be included in the authority application.

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate.

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life.
### Antineoplastic and Immunomodulating Agents

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<th>Code</th>
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**Tacrolimus**

**Authority required**
Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

**Caution**
Careful monitoring of patients is mandatory.

<table>
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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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**Other immunosuppressants**

**Azathioprine**

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

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**METHOTREXATE**

*Restricted benefit*

For patients requiring doses greater than 20 mg per week
### MUSCULO-SKELETAL SYSTEM

#### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

**Acetic acid derivatives and related substances**

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**DICLOFENAC**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

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### INDOMETHACIN
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<td>*22.84</td>
<td>23.99</td>
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**INDOMETHACIN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

<table>
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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<td>14.35</td>
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</table>

**Oxicams**

**MELOXICAM**

**Restricted benefit**

Symptomatic treatment of osteoarthritis

**Restricted benefit**

Symptomatic treatment of rheumatoid arthritis

**Note**

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Note**

Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

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<td>15.43</td>
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**MELOXICAM**

**Restricted benefit**

Symptomatic treatment of osteoarthritis

**Restricted benefit**

Symptomatic treatment of rheumatoid arthritis
### MUSCULO-SKELETAL SYSTEM

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<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</table>

**Note**

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;

(b) soft tissue injury;

(c) arthrosis without an inflammatory component.

**Note**

Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

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<th>Maximum Recordable Value for Safety Net $</th>
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**PIROXICAM**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

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<th>Code</th>
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**Note**

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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>a Mobilis D-20</td>
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**Propionic acid derivatives**

**IBUPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3190X</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*15.07</td>
<td>16.22</td>
<td>Brufen GO</td>
</tr>
<tr>
<td>5123P</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*15.07</td>
<td>16.22</td>
<td>Brufen GO</td>
</tr>
<tr>
<td>3192B</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>9.53</td>
<td>10.68</td>
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<tr>
<td>5124Q</td>
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<td>..</td>
<td>..</td>
<td>9.53</td>
<td>10.68</td>
<td>Brufen GO</td>
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**KETOPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>*25.64</td>
<td>26.79</td>
<td>Orudis SW</td>
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<tr>
<td>5139L</td>
<td>ketoprofen 100 mg suppository, 20</td>
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<td>..</td>
<td>..</td>
<td>*25.64</td>
<td>26.79</td>
<td>Orudis SW</td>
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**KETOPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

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<td>19.44</td>
<td>20.59</td>
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**NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

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<td>a Proxen SR 1000 MD</td>
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<td>13.57</td>
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<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>a Naprosyn SR750 RO</td>
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</tbody>
</table>

**NAPROXEN**

**Authority required (STREAMLINED)**

4159 Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

The condition must have an inflammatory component,

AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority required (STREAMLINED)**

4124 Bone pain

**Clinical criteria:**

The condition must be due to malignant disease,

AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

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<tr>
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<tr>
<td>DP</td>
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<td>..</td>
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<td>13.57</td>
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<td>12.42</td>
<td>13.57</td>
<td>a Proxen SR 750 MD</td>
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</table>

**NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

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<th>Code</th>
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<td>14.26</td>
<td>a Crysanal</td>
<td>MD</td>
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<td>18.50</td>
<td>19.65</td>
<td>Ponstan</td>
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**Fenamates**

**MEFENAMIC ACID**

**Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>mefenamic acid 250 mg capsule, 50</td>
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<td>2</td>
<td>18.50</td>
<td>19.65</td>
<td>Ponstan</td>
<td>PF</td>
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</table>

**Coxibs**

**CELECOXIB**

**Restricted benefit**

Symptomatic treatment of osteoarthritis

**Restricted benefit**

Symptomatic treatment of rheumatoid arthritis

**Note**

The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;

(b) soft tissue injury;
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8439E NP</td>
<td>celecoxib 100 mg capsule, 60</td>
<td>1 3</td>
<td>..</td>
<td>28.51</td>
<td>29.66</td>
<td>a</td>
<td>APO-Celecoxib TX</td>
</tr>
<tr>
<td>8440F NP</td>
<td>celecoxib 200 mg capsule, 30</td>
<td>1 3</td>
<td>..</td>
<td>28.51</td>
<td>29.66</td>
<td>a</td>
<td>APO-Celecoxib TX</td>
</tr>
</tbody>
</table>

**SPECIFIC ANTIRHEUMATIC AGENTS**

**Quinolines**

**HYDROXYCHLOROQUINE**

**Note**

Shared Care Model:

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

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<tr>
<td>1512N NP</td>
<td>hydroxychloroquine sulfate 200 mg tablet, 100</td>
<td>1 1</td>
<td>..</td>
<td>30.24</td>
<td>31.39</td>
<td>a</td>
<td>APO-Hydroxychloroquine TX</td>
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</table>

**Gold preparations**

**AURANOFIN**

**Caution**

Regular blood and urine checks are essential.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>2022K NP</td>
<td>AURANOFIN Capsule 3 mg, 60</td>
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<td>779.33</td>
<td>37.70</td>
<td>Ridaura GH</td>
<td></td>
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**AURANOFIN**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised...
## MUSCULO-SKELETAL SYSTEM

### MUSCLE RELAXANTS

#### CENTRALLY ACTING AGENTS

**BACLOFEN**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>2729P</td>
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<td>1</td>
<td>5</td>
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<td>19.59</td>
<td>20.74</td>
<td>Chem mart Baclofen</td>
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#### DIRECTLY ACTING AGENTS

**DANTROLENE**

**Restricted benefit**

Treatment of chronic spasticity

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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>1779P</td>
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<td>37.70</td>
<td>Dantrium</td>
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<tr>
<td>1780Q</td>
<td>dantrolene sodium 50 mg capsule, 100</td>
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<td>2</td>
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<td>82.15</td>
<td>37.70</td>
<td>Dantrium</td>
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---

**AUROTHIOMALATE SODIUM**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

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

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<td>2016D</td>
<td>aurothiomalate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
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<td>..</td>
<td>83.64</td>
<td>37.70</td>
<td>Myocrisin SW</td>
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<tr>
<td>2017E</td>
<td>aurothiomalate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
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<td>1</td>
<td>..</td>
<td>125.03</td>
<td>37.70</td>
<td>Myocrisin SW</td>
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<tr>
<td>2018F</td>
<td>aurothiomalate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
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<td>1</td>
<td>..</td>
<td>152.81</td>
<td>37.70</td>
<td>Myocrisin SW</td>
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</table>

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**Penicillamine and similar agents**

**PENICILLAMINE**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

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<td>2838J</td>
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<td>1</td>
<td>..</td>
<td>53.63</td>
<td>37.70</td>
<td>D-Penamine AL</td>
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### ANTIGOUT PREPARATIONS

#### Preparations inhibiting uric acid production

**ALLOPURINOL**

**Note**

The dose should be adjusted in accordance with renal function.

**Note**

For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

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<td>2600W</td>
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<td>2</td>
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<td>11.31</td>
<td>12.46</td>
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**Preparations increasing uric acid excretion**

**PROBENECID**

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**Preparations with no effect on uric acid metabolism**

**COLCHICINE**

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### DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

**ALENDRONATE**

*Authority required (STREAMLINED)*

4122

Corticosteroid-induced osteoporosis

**Clinical criteria:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4133

Osteoporosis

**Clinical criteria:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

**Population criteria:**

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4123

Established osteoporosis

**Clinical criteria:**

Patient must have fracture due to minimal trauma,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

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**CLODRONATE**

**Restricted benefit**

Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Restricted benefit**

Multiple myeloma

**Restricted benefit**

Bone metastases from breast cancer

**Note**

Continuing Therapy Only:

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

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### MUSCULO-SKELETAL SYSTEM

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**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

---

### RISEDRONATE

**Authority required (STREAMLINED)**

**Symptomatic Paget disease of bone**

**Note**

Continuing Therapy Only:

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

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### TILUDRONATE

**Authority required (STREAMLINED)**

**Symptomatic Paget disease of bone**

**Note**

Continuing Therapy Only:

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

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### ZOLEDRONIC ACID

**Authority required (STREAMLINED)**

**4100**
Corticosteroid-induced osteoporosis

**Clinical criteria:**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
- AND
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
- AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
- AND
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**4149**
Osteoporosis

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less,
- AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
- AND
- Patient must not receive more than one PBS-subsidised treatment per year.

**Population criteria:**
- Patient must be aged 70 years or older.
- The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**4157**
Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma,
- AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
- AND
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

### ZOLEDRONIC ACID

**Authority required**

Symptomatic Paget disease of bone.

Only 1 treatment each year per patient will be PBS-subsidised
Bisphosphonates, combinations

ALENDRONATE + COLECALCIFEROL
Authority required (STREAMLINED)

4122
Corticosteroid-induced osteoporosis

Clinical criteria:
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
AND
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

4133
Osteoporosis

Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:
Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

4123
Established osteoporosis

Clinical criteria:
Patient must have fracture due to minimal trauma,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.
MUSCULO-SKELETAL SYSTEM

<table>
<thead>
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Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
  AND
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
  AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4110
Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
  AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.
  The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4087
Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma,
  AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

- Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

- Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

9012H
alendronate 70 mg + colecalciferol 70 microgram tablet, 4

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A LENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

Authority required (STREAMLINED)

4122
Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
  AND
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
  AND
**MUSCULO-SKELETAL SYSTEM**

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- **Clinical criteria:**

  Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

  **AND**

  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

  **Population criteria:**

  Patient must be aged 70 years or older.

  The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

  **Clinical criteria:**

  Patient must have fracture due to minimal trauma,

  **AND**

  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

  **Note**

  Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

  **RISEDRONATE (&) CALCIUM CARBONATE**

  **Authority required (STREAMLINED)**

  **Clinical criteria:**

  Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

  **AND**

  Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

  **AND**

  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

  The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

  **Authority required (STREAMLINED)**

  **Clinical criteria:**

  Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
### MUSCULO-SKELETAL SYSTEM

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**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

**Population criteria:**

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4123

Established osteoporosis

**Clinical criteria:**

Patient must have fracture due to minimal trauma,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1‡1‑5...

45.73 37.70

Actonel EC Combi UA

**RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**

**Authority required (STREAMLINED)**

4122

Corticosteroid-induced osteoporosis

**Clinical criteria:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4133

Osteoporosis

**Clinical criteria:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

**Population criteria:**

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4123
Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Other drugs affecting bone structure and mineralization

CALCITRIOL

Authority required (STREAMLINED)

Hypocalcaemia due to renal disease

Authority required (STREAMLINED)

Hypoparathyroidism

Authority required (STREAMLINED)

Hypophosphataemic rickets

Authority required (STREAMLINED)

Vitamin D-resistant rickets

Authority required (STREAMLINED)

Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

DENOSUMAB

Authority required (STREAMLINED)

Giant cell tumour of bone

Clinical criteria:

Patient must be one in whom surgical resection is not feasible; OR
Population criteria:

Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

Population criteria:

Patient must be an adult; OR

Patient must be a skeletally mature adolescent.

Note

Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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<td>..</td>
<td>296.00</td>
<td>37.70</td>
<td>Prolia</td>
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</table>

**RALOXIFENE**

**Authority required (STREAMLINED)**

4071

Established post-menopausal osteoporosis

**Clinical criteria:**

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**STRONTIUM**

**Authority required**

Severe established osteoporosis

**Clinical criteria:**

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,

AND

Patient must be at high risk of fracture,

AND

Patient must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride,
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<tbody>
<tr>
<td>3036T</td>
<td>strontium ranelate and zoledronic acid.</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>52.00</td>
<td>37.70</td>
<td>Protos 2 g</td>
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</tbody>
</table>

**TERIPARATIDE**

*Authority required*

Severe established osteoporosis

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must be at very high risk of fracture,
- AND
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less,
- AND
- Patient must have had 2 or more fractures due to minimal trauma,
- AND
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,
- AND
- The treatment must be the sole PBS-subsidised agent,
- AND
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note**

Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

*Authority required*

Severe established osteoporosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug,
- AND
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note**
Up to a maximum of 18 pens will be reimbursed through the PBS.

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

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

**Note**
Special Pricing Arrangements apply.

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<td>teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge</td>
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<td>438.71</td>
<td>37.70</td>
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### ANALGESICS

#### OPIOIDS

**Natural opium alkaloids**

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<td>codeine phosphate 30 mg tablet, 20 kg</td>
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<td>17.21</td>
<td>18.36</td>
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<td>Fawns and McAllan Proprietary Limited</td>
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**CODEINE**

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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<td>18.36</td>
<td>..</td>
<td>Fawns and McAllan Proprietary Limited</td>
</tr>
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</table>

**HYDROMORPHONE**

**Restricted benefit**
Severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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<td>hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL</td>
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<td>30.37</td>
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<td>Dilaudid</td>
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**HYDROMORPHONE**

**Restricted benefit**
Severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8424J</td>
<td>hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL</td>
<td>1</td>
<td>..</td>
<td>64.04</td>
<td>37.70</td>
<td>..</td>
<td>Dilaudid</td>
</tr>
<tr>
<td>8541M</td>
<td>hydromorphone hydrochloride 2 mg tablet, 20 kg</td>
<td>1</td>
<td>..</td>
<td>17.45</td>
<td>18.60</td>
<td>..</td>
<td>Dilaudid</td>
</tr>
<tr>
<td>8542N</td>
<td>hydromorphone hydrochloride 4 mg tablet, 20 kg</td>
<td>1</td>
<td>..</td>
<td>20.19</td>
<td>21.34</td>
<td>..</td>
<td>Dilaudid</td>
</tr>
<tr>
<td>8543P</td>
<td>hydromorphone hydrochloride 8 mg tablet, 20 kg</td>
<td>1</td>
<td>..</td>
<td>30.37</td>
<td>31.52</td>
<td>..</td>
<td>Dilaudid</td>
</tr>
</tbody>
</table>

**HYDROMORPHONE**

**Caution**
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8421F</td>
<td>hydromorphone hydrochloride 10 mg/mL oral liquid, 473 mL</td>
<td>1</td>
<td>..</td>
<td>29.31</td>
<td>30.46</td>
<td>..</td>
<td>Dilaudid-HP</td>
</tr>
</tbody>
</table>
Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer
---|-------------------|-----------------|-------------|------------|------------------|-----------------------------|------------------
NP  | morphine Capsule 10 mg (containing sustained release pellets), 28 | 1 | .. | .. | 20.37 | 21.52 | Kapanol
NP  | morphine Capsule 50 mg (containing sustained release pellets), 28 | 1 | .. | .. | 25.35 | 26.50 | Kapanol
NP  | morphine Capsule 20 mg (containing sustained release pellets), 28 | 1 | .. | .. | 43.65 | 37.70 | Kapanol
NP  | morphine Capsule 50 mg (containing sustained release pellets), 28 | 1 | .. | .. | 31.29 | 32.44 | Jurnista
NP  | morphine 30 mg per sachet, 28 | 1 | .. | .. | 37.70 | 37.70 | MS Contin Suspension

**MORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

NP  | morphine Capsule 100 mg (containing sustained release pellets), 28 | 1 | .. | .. | 20.37 | 21.52 | Kapanol
NP  | morphine Capsule 200 mg (containing sustained release pellets), 28 | 1 | .. | .. | 25.35 | 26.50 | Kapanol
NP  | morphine Capsule 500 mg (containing sustained release pellets), 28 | 1 | .. | .. | 43.65 | 37.70 | Kapanol
NP  | morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28 | 1 | .. | .. | 62.41 | 37.70 | MS Contin Suspension

**HYDROMORPHONE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
NERVOUS SYSTEM

Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | --- | ---
8305D | morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28 | 1 | .. | .. | 70.21 | 37.70 | MS Contin Suspension 60 mg
1653B | morphine sulfate 10 mg tablet: modified release, 28 tablets | 1 | .. | .. | 20.38 | 21.53 | a Momex SR 10 QA
8306E | morphine sulfate 100 mg granules: modified release, 28 sachets | 1 | .. | .. | 86.71 | 37.70 | a MS Contin Susp 100 mg MF
1656E | morphine sulfate 100 mg tablet: modified release, 28 tablets | 1 | .. | .. | 72.85 | 37.70 | a MS Contin MF
8494C | morphine sulfate 120 mg capsule: modified release, 14 capsules | 1 | .. | .. | 54.81 | 37.70 | MS Mono MF
8497T | morphine sulfate 15 mg tablet: modified release, 28 tablets | 1 | .. | .. | 24.57 | 25.72 | MS Contin MF
8490W | morphine sulfate 20 mg granules: modified release, 28 sachets | 1 | .. | .. | 60.63 | 37.70 | MS Contin Susp 20 mg MF
8491X | morphine sulfate 30 mg capsule: modified release, 14 capsules | 1 | .. | .. | 24.56 | 25.71 | MS Mono MF
1654C | morphine sulfate 30 mg tablet: modified release, 28 tablets | 1 | .. | .. | 36.23 | 37.38 | a Momex SR 30 QA
8035X | morphine sulfate 5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 17.95 | 19.10 | MS Contin MF
8492Y | morphine sulfate 60 mg capsule: modified release, 14 capsules | 1 | .. | .. | 36.21 | 37.36 | MS Mono MF
1655D | morphine sulfate 60 mg tablet: modified release, 28 tablets | 1 | .. | .. | 54.82 | 37.70 | a Momex SR 60 QA
8493B | morphine sulfate 90 mg capsule: modified release, 14 capsules | 1 | .. | .. | 41.76 | 37.70 | a MORPHINE MR APOTEX TX MS Contin MF

MORPHINE

Restricted benefit
Severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

2124T | morphine hydrochloride 10 mg/mL oral liquid, 200 mL | 1 | .. | .. | 27.20 | 28.35 | Ordine 10 MF
2122Q | morphine hydrochloride 2 mg/mL oral liquid, 200 mL | 1 | .. | .. | 20.67 | 21.82 | Ordine 2 MF
2123R | morphine hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | .. | .. | 23.07 | 24.22 | Ordine 5 MF
1646P | morphine sulfate 30 mg tablet, 20 | 1 | .. | .. | 14.37 | 15.52 | Anamorph FM

MORPHINE

Restricted benefit
Severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### MORPHINE

**Restricted benefit**
Severe disabling pain due to cancer not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5239R</td>
<td>morphine hydrochloride 10 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>27.20</td>
<td>28.35</td>
<td>Ordine 10 (MF)</td>
</tr>
<tr>
<td>5237P</td>
<td>morphine hydrochloride 2 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.67</td>
<td>21.82</td>
<td>Ordine 2 (MF)</td>
</tr>
<tr>
<td>5238Q</td>
<td>morphine hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>23.07</td>
<td>24.22</td>
<td>Ordine 5 (MF)</td>
</tr>
<tr>
<td>5163R</td>
<td>morphine sulfate 30 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.37</td>
<td>15.52</td>
<td>Anamorph (FM)</td>
</tr>
</tbody>
</table>

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### MORPHINE

**Caution**
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8669G</td>
<td>morphine sulfate 10 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.66</td>
<td>15.81</td>
<td>Sevredol (MF)</td>
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<tr>
<td>8670H</td>
<td>morphine sulfate 20 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>15.60</td>
<td>16.75</td>
<td>Sevredol (MF)</td>
</tr>
</tbody>
</table>

### MORPHINE

**Caution**
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1644M</td>
<td>morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>16.76</td>
<td>17.91</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
<tr>
<td>1645N</td>
<td>morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.30</td>
<td>18.45</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
<tr>
<td>1647Q</td>
<td>morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>19.43</td>
<td>20.58</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
<tr>
<td>1607N</td>
<td>morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>39.62</td>
<td>37.70</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
</tbody>
</table>

### MORPHINE

**Caution**
The risk of drug dependence is high.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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</thead>
<tbody>
<tr>
<td>5168B</td>
<td>morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>16.76</td>
<td>17.91</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
<tr>
<td>5169C</td>
<td>morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.30</td>
<td>18.45</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
<tr>
<td>5170D</td>
<td>morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>19.43</td>
<td>20.58</td>
<td>Hospira Pty Limited (HH)</td>
</tr>
</tbody>
</table>

### MORPHINE

**Authority required**
Chronic severe disabling pain due to cancer

**Caution**
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8454Y</td>
<td>morphine sulfate 200 mg granules: modified release, 28 sachets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>164.09</td>
<td>37.70</td>
<td>MS Contin Suspension 200 mg (MF)</td>
</tr>
<tr>
<td>8453X</td>
<td>morphine sulfate 200 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>122.20</td>
<td>37.70</td>
<td>MS Contin (MF)</td>
</tr>
</tbody>
</table>

### OXICODONE

**Restricted benefit**
Severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or
### OXYCODONE

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5194J</td>
<td>oxycodone 30 mg suppository, 12</td>
<td>1 ...</td>
<td>44.00</td>
<td>37.70</td>
<td>Proladone PL</td>
</tr>
<tr>
<td>5197M</td>
<td>oxycodone hydrochloride 10 mg capsule, 20</td>
<td>1 ...</td>
<td>14.76</td>
<td>15.91</td>
<td>OxyNorm MF</td>
</tr>
<tr>
<td>5191F</td>
<td>oxycodone hydrochloride 5 mg capsule, 20</td>
<td>1 ...</td>
<td>12.14</td>
<td>13.29</td>
<td>OxyNorm MF</td>
</tr>
<tr>
<td>5195K</td>
<td>oxycodone hydrochloride 5 mg tablet, 20</td>
<td>1 ...</td>
<td>12.14</td>
<td>13.29</td>
<td>Endone QA</td>
</tr>
<tr>
<td>5190E</td>
<td>oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL</td>
<td>1 ...</td>
<td>21.07</td>
<td>22.22</td>
<td>OxyNorm Liquid 5mg/5mL MF</td>
</tr>
</tbody>
</table>

### Clinical criteria:
The condition must be unresponsive to non-narcotic analgesics.

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.
## NERVOUS SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9399Q</td>
<td>oxycodone hydrochloride 15 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>31.60</td>
<td>32.75</td>
<td>OxyContin</td>
</tr>
<tr>
<td>8386J</td>
<td>oxycodone hydrochloride 20 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>36.22</td>
<td>37.37</td>
<td>Oxycodone Sandoz</td>
</tr>
<tr>
<td>9400R</td>
<td>oxycodone hydrochloride 30 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>46.79</td>
<td>37.70</td>
<td>OxyContin</td>
</tr>
<tr>
<td>8387K</td>
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<td>..</td>
<td>..</td>
<td>54.81</td>
<td>37.70</td>
<td>Oxycodone Sandoz</td>
</tr>
<tr>
<td>8388L</td>
<td>oxycodone hydrochloride 80 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>83.05</td>
<td>37.70</td>
<td>Oxycodone Sandoz</td>
</tr>
</tbody>
</table>

**OXYCODONE + NALOXONE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

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(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

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

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8934F</td>
<td>oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>31.01</td>
<td>32.16</td>
<td>Targin 10/5mg</td>
</tr>
<tr>
<td>8935G</td>
<td>oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>47.19</td>
<td>37.70</td>
<td>Targin 20/10mg</td>
</tr>
<tr>
<td>8936H</td>
<td>oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>73.62</td>
<td>37.70</td>
<td>Targin 40/20mg</td>
</tr>
<tr>
<td>8000C</td>
<td>oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.71</td>
<td>30.86</td>
<td>Targin 5/2.5mg</td>
</tr>
</tbody>
</table>

**PARACETAMOL + CODEINE**

**Note**

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below.

<table>
<thead>
<tr>
<th>Code</th>
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**PARACETAMOL + CODEINE**
### NERVOUS SYSTEM

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<th>Max. Qty (Packs)</th>
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#### PARACETAMOL + CODEINE

**Authority required**
Severe disabling pain not responding to non-narcotic analgesics

**Note**
Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

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<thead>
<tr>
<th>Code</th>
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#### Phenylpiperidine derivatives

**FENTANYL**

**Restricted benefit**
Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour). Pharmaceutical benefits that have the forms fentanyl transdermal patch 16.5 mg, fentanyl transdermal patch 10.20 mg and fentanyl transdermal patch 16.8 mg (all releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.

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**FENTANYL**

**Restricted benefit**
Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 2.063 mg, fentanyl transdermal patch 1.28 mg and fentanyl transdermal patch 2.1 mg (all releasing approximately 12 micrograms per hour) are equivalent for the purposes of substitution.

**Fentanyl**

**Restricted benefit**
Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 4.125 mg, fentanyl transdermal patch 2.55 mg and fentanyl transdermal patch 4.2 mg (all releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 8.25 mg, fentanyl transdermal patch 5.10 mg and fentanyl transdermal patch 8.4 mg (all releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.

<table>
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<th>Code</th>
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**FENTANYL**

**Restricted benefit**
Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

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(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 12.375 mg, fentanyl transdermal patch 7.65 mg and fentanyl transdermal patch 12.6 mg (all releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

<table>
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<td>37.70</td>
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**Diphenylpropylamine derivatives**

**METHADONE**

**Restricted benefit**
Severe disabling pain not responding to non-narcotic analgesics
## NERVOUS SYSTEM

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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### Oripavine derivatives

**BUPRENORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

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(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

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

**Oripavine derivatives**

**BUPRENORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

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

**Other opioids**

**TAPENTADOL**

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**Caution**

The risk of drug dependence is high.
### NERVOUS SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

---

**TRAMADOL**

**Restricted benefit**
For pain where aspirin and/or paracetamol alone are inappropriate or have failed

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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**Note**

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
### NERVOUS SYSTEM

#### TRAMADOL

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#### Note

No applications for increased maximum quantities and/or repeats will be authorised.

---

**TRAMADOL**

**Restricted benefit**

Short-term treatment of acute pain

---

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
### NERVOUS SYSTEM

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*Note:*

No applications for increased maximum quantities and/or repeats will be authorised.
## NERVOUS SYSTEM

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### Other analgesics and antipyretics

#### PREGABALIN

**Authority required (STREAMLINED)**

4172

Neuropathic pain

**Clinical criteria:**

The condition must be refractory to treatment with other drugs.

**Note**

**Continuing Therapy Only:**

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

<table>
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### ANTIMIGRAINE PREPARATIONS

#### Selective serotonin (5HT1) agonists

#### ELETRIPTAN

**Authority required (STREAMLINED)**

4573

Migraine attack

**Clinical criteria:**

The condition must have usually failed to respond to analgesics in the past.

**Caution**

Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

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

**Note**
NERVOUS SYSTEM

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

**Note**

**Continuing Therapy Only:**
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**NARATRIPTAN**

**Authority required**

Migraine attack

**Clinical criteria:**
The condition must have usually failed to respond to analgesics in the past.

**Caution**

Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

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

**Note**

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

**Note**

**Continuing Therapy Only:**
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**NARATRIPTAN**

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are expected to occur with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences

**Caution**

Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

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

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**RIZATRIPTAN**

**Authority required (STREAMLINED)**

4573
NERVOUS SYSTEM

Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Caution
Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

Note
Continuing Therapy Only:
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SUMATRIPTAN
Authority required (STREAMLINED)

4558
Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Caution
Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

Note
Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note
Continuing Therapy Only:
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ZOMITRIPTAN

Authority required (STREAMLINED)

4573

Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Caution
Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

Note
Continuing Therapy Only:
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Other antimigraine preparations

CYPROHEPTADINE

Restricted benefit
Prevention of migraine

Note
Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note
Continuing Therapy Only:
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PIZOTIFEN

Note
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ANTIEPILEPTICS

Barbiturates and derivatives

PHENOBARBITONE

Restricted benefit
Epilepsy

Note
Continuing Therapy Only:
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### NERVOUS SYSTEM

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<td>39.36</td>
<td>37.70</td>
<td>Fawns and McAllan Proprietary Limited FM</td>
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**PRIMIDONE**

**Note**

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**Hydantoin derivatives**

**PHENYTOIN**

**Note**

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<td>3</td>
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<td>1873N</td>
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**Succinimide derivatives**

**ETHOSUXTIMIDE**

**Note**

Continuing Therapy Only:

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<td>37.70</td>
<td>Zarontin PF</td>
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<tr>
<td>1414K</td>
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<td>‡1</td>
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<td>29.43</td>
<td>30.58</td>
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**Benzodiazepine derivatives**

**CLONAZEPAM**

**Restricted benefit**

Epilepsy

**Note**

Continuing Therapy Only:

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<tr>
<td>1807D</td>
<td>clonazepam 1 mg/mL injection [5 x 1 mL ampoules] [6] inert substance diluent [5 x 1 mL ampoules], 1 pack</td>
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<td>..</td>
<td>..</td>
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<td>20.07</td>
<td>Rivotril RO</td>
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</table>

**CLONAZEPAM**

**Authority required**

Neurologically proven epilepsy

**Caution**

Abuse of clonazepam has been reported. Refer to the current product information.

**Note**

Continuing Therapy Only:

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<td>1806C</td>
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<td>*$1.40</td>
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### NERVOUS SYSTEM

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<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
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<td>35.26</td>
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<tr>
<td>1805B</td>
<td>clonazepam 500 microgram tablet, 100</td>
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<td>2</td>
<td>..</td>
<td>3.42</td>
<td>23.26</td>
<td>Rivotril RO</td>
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</tbody>
</table>

### NITRAZEPAM

**Authority required**
Myoclonic epilepsy

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**
Continuing Therapy Only:
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<td>2732T</td>
<td>nitrazepam 5 mg tablet, 25</td>
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<td>5</td>
<td>..</td>
<td>2.48</td>
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<td>Mogadon IA</td>
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### CARBOXAMIDE DERIVATIVES

### CARBAMAZEPINE

**Note**
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<td>2422L</td>
<td>CARBAMAZEPINE Tablet 100 mg, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>2.96</td>
<td>18.84</td>
<td>Tegretol 100 NV</td>
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### CARBAMAZEPINE

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<td>..</td>
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<td>18.84</td>
<td>Tegretol 100 NV</td>
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<tr>
<td>5041H</td>
<td>carbamazepine 100 mg/5 mL oral liquid, 300 mL</td>
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<td>..</td>
<td>..</td>
<td>2.96</td>
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<td>Tegretol Liquid NV</td>
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<td>5038E</td>
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<td>2.96</td>
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<td>37.70</td>
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<td>5037D</td>
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<td>1</td>
<td>..</td>
<td>..</td>
<td>2.96</td>
<td>49.37</td>
<td>37.70</td>
</tr>
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</table>

### CARBAMAZEPINE

**Note**
For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Note**
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<td>Tegretol 200 NV</td>
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<tr>
<td>2419H</td>
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<td>2</td>
<td>..</td>
<td>2.96</td>
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<td>Teril AF</td>
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### NERVOUS SYSTEM

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<td>..</td>
<td>..</td>
<td>$29.33</td>
<td>30.48</td>
<td>a Teril</td>
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### CARBAMAZEPINE

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<td>2426Q NP</td>
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<td>..</td>
<td>49.37</td>
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### OXCARBAZEPINE

**Authority required (STREAMLINED)**
1587
Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs

**Note**
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<td>..</td>
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<td>8585W NP</td>
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<td>2</td>
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<td>37.70</td>
<td>Trileptal</td>
</tr>
<tr>
<td>8588B NP</td>
<td>oxcarbazepine 60 mg/mL oral liquid, 250 mL</td>
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<td>5</td>
<td>..</td>
<td>*138.46</td>
<td>37.70</td>
<td>Trileptal</td>
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<tr>
<td>8586X NP</td>
<td>oxcarbazepine 600 mg tablet, 100</td>
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<td>5</td>
<td>..</td>
<td>188.32</td>
<td>37.70</td>
<td>Trileptal</td>
</tr>
</tbody>
</table>

### Fatty acid derivatives

#### TIAGabINE

**Authority required (STREAMLINED)**
2664
Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**
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<td>8222R NP</td>
<td>tiagabine 10 mg tablet, 50</td>
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<td>5</td>
<td>..</td>
<td>*139.18</td>
<td>37.70</td>
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<td>8223T NP</td>
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<td>5</td>
<td>..</td>
<td>*197.24</td>
<td>37.70</td>
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<tr>
<td>8221Q NP</td>
<td>tiagabine 5 mg tablet, 50</td>
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<td>5</td>
<td>..</td>
<td>*72.96</td>
<td>37.70</td>
<td>Gabitril</td>
</tr>
</tbody>
</table>

### VALPROATE

**Caution**
There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

**Note**
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<td>*32.34</td>
<td>33.49</td>
<td>Epilim</td>
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<td>2289L NP</td>
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### Oxcarbazepine (Continued)

**Authority required (STREAMLINED)**
1587
Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs

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

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**VIGABATRIN**

**Authority required (STREAMLINED)**

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Caution**

Visual field defects have been reported with this drug.

**Note**

Continuing Therapy Only:

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**Other antiepileptics**

**GABAPENTIN**

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

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**LACOSAMIDE**

**Authority required (STREAMLINED)**

4271

Intractable partial epileptic seizures

**Treatment Phase: Initial**

**Clinical criteria:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents,

AND

The treatment must be for dose titration purposes.

**Population criteria:**

Patient must be aged 16 years or older.

**Treatment criteria:**

Must be treated by a neurologist.

**Note**

Continuing Therapy Only:

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

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**LACOSAMIDE**

**Authority required (STREAMLINED)**

4264

Intractable partial epileptic seizures

**Treatment Phase: Initial**

**Clinical criteria:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,
## NERVOUS SYSTEM

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### LACOSAMIDE

**Authority required (STREAMLINED)**

4240  
Intractable partial epileptic seizures  
Treatment Phase: Initial

**Clinical criteria:**  
The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,  
AND  
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**  
Patient must be aged 16 years or older.

**Treatment criteria:**  
Must be treated by a neurologist.

**Note**  
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### LAMOTRIGINE

**Authority required (STREAMLINED)**

9338L  
lacosamide 200 mg tablet, 56  
1 5 355.72 37.70 Vimpat UC

**Note**  
No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

**Note**  
Continuing Therapy Only:  
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**LEVETIRACETAM**  
*Authority required (STREAMLINED)*  
2664  
Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs  

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

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**LEVETIRACETAM**

**Authority required (STREAMLINED)**

3291

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam

**Note**

**Continuing Therapy Only:**

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

**PERAMPANEL**

**Authority required (STREAMLINED)**

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug.

**Note**

**Continuing Therapy Only:**

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

Note
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TOPIRAMATE

Authority required (STREAMLINED)
2798
Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs

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

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<td>Topiramate Sandoz SZ</td>
</tr>
</tbody>
</table>

TOPIRAMATE

Authority required (STREAMLINED)
2799
Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs

Authority required (STREAMLINED)
2799
Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:
(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
NERVOUS SYSTEM

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<td>8163P</td>
<td>topiramate 25 mg tablet, 60</td>
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<td>23.90</td>
<td>APO-Topiramate TX</td>
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ZONISAMIDE

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

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

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<tr>
<td>9390F</td>
<td>zonisamide 100 mg capsule, 56</td>
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<td>5</td>
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<td>*93.80</td>
<td>37.70</td>
<td>Zonegran SA</td>
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<td>9388D</td>
<td>zonisamide 25 mg capsule, 56</td>
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<td>23.14</td>
<td>24.29</td>
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<td>5</td>
<td>..</td>
<td>34.06</td>
<td>35.21</td>
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ANTI-PARKINSON DRUGS

**ANTICHOLINERGIC AGENTS**

**Tertiary amines**

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<tr>
<td>1109J</td>
<td>benzhexol hydrochloride 2 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>15.66</td>
<td>16.81</td>
<td>Artane QA</td>
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<tr>
<td>1110K</td>
<td>benzhexol hydrochloride 5 mg tablet, 200</td>
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<td>1</td>
<td>..</td>
<td>22.35</td>
<td>23.50</td>
<td>Artane QA</td>
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**BIPERIDEN**

**Note**

Continuing Therapy Only:

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2544X</td>
<td>biperiden hydrochloride 2 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*21.22</td>
<td>22.37</td>
<td>Akineton LM</td>
</tr>
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</table>

**Ethers of tropine or tropine derivatives**

- (b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker;
- AND
- (c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- (d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient’s medical records when treatment is initiated.

**Note**

Continuing Therapy Only:

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### NERVOUS SYSTEM

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<td>2362H</td>
<td>benztropine mesylate 2 mg tablet, 60</td>
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<td>15.47</td>
<td>16.62</td>
<td>Benztrop</td>
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<td>10013B</td>
<td>benztropine mesylate 2 mg/2 mL injection, 10 \times 2 mL vials</td>
<td>1</td>
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<td>287.65</td>
<td>37.70</td>
<td>Benztrop Omega</td>
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<tr>
<td>10027R</td>
<td>benztropine mesylate 2 mg/2 mL injection, 5 \times 2 mL ampoules</td>
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<td>..</td>
<td>287.65</td>
<td>37.70</td>
<td>Benztrop Omega</td>
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<tr>
<td>3038X</td>
<td>benztropine mesylate 2 mg/2 mL injection, 5 \times 2 mL ampoules</td>
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<td>..</td>
<td>103.93</td>
<td>37.70</td>
<td>Cogentin</td>
</tr>
<tr>
<td>5031T</td>
<td>benztropine mesylate 2 mg/2 mL injection, 5 \times 2 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>103.93</td>
<td>37.70</td>
<td>Cogentin</td>
</tr>
</tbody>
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#### DOPAMINERGIC AGENTS

**Dopa and dopa derivatives**

**LEVODOPA + BENSERAZIDE**

**Note**
- Continuing Therapy Only:

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<tr>
<td>8219N</td>
<td>LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100</td>
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<td>5</td>
<td>39.26</td>
<td>37.70</td>
<td>Madopar Rapid 125</td>
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<tr>
<td>8218M</td>
<td>LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100</td>
<td>1</td>
<td>5</td>
<td>23.34</td>
<td>24.49</td>
<td>Madopar Rapid 62.5</td>
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<tr>
<td>2225D</td>
<td>levodopa 100 mg + benzerazide 25 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>39.26</td>
<td>37.70</td>
<td>Madopar 125</td>
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<td>2231K</td>
<td>levodopa 100 mg + benzerazide 25 mg capsule: modified release, 100</td>
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<td>42.34</td>
<td>37.70</td>
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<td>37.70</td>
<td>Madopar 125</td>
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<td>37.70</td>
<td>Madopar</td>
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<td>2228G</td>
<td>levodopa 200 mg + benzerazide 50 mg tablet, 100</td>
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<td>5</td>
<td>50.35</td>
<td>37.70</td>
<td>Madopar</td>
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<td>2227F</td>
<td>levodopa 50 mg + benzerazide 12.5 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>23.34</td>
<td>24.49</td>
<td>Madopar 62.5</td>
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**LEVODOPA + CARBIDOPA ANHYDROUS**

**Note**
- Continuing Therapy Only:

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<tr>
<td>1242J</td>
<td>levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>38.63</td>
<td>37.70</td>
<td>Kinson</td>
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<td>1245M</td>
<td>levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>45.43</td>
<td>37.70</td>
<td>Sinemet</td>
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</tbody>
</table>

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required**

Maintenance therapy following treatment which was commenced in a hospital-based movement disorder clinic, of a patient with advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy

**Note**
- Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note**
- Shared Care Model:

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

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<tr>
<td>8970D</td>
<td>levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags</td>
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<td>5</td>
<td>11682.68</td>
<td>37.70</td>
<td>Duodopa</td>
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**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required (STREAMLINED)**

1257
### NERVOUS SYSTEM

**Code**
**Name, Restriction, Manner of Administration and Form**
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<tr>
<td>1255C</td>
<td>levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets</td>
<td>1</td>
<td>5</td>
<td>68.21</td>
<td>37.70</td>
<td>Sinemet CR MK</td>
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</tbody>
</table>

**LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**

**Authority required (STREAMLINED)**

**3305**

Parkinson disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

**Authority required (STREAMLINED)**

**3306**

Parkinson disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone

**Note**

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<td>8798C</td>
<td>levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100</td>
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<td>4</td>
<td>*342.26</td>
<td>37.70</td>
<td>Stalevo 100/25/200mg NV</td>
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<td>9245W</td>
<td>levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100</td>
<td>2</td>
<td>4</td>
<td>*354.30</td>
<td>37.70</td>
<td>Stalevo 125/31.25/200mg NV</td>
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<td>8799D</td>
<td>levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100</td>
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<td>4</td>
<td>*372.30</td>
<td>37.70</td>
<td>Stalevo 150/37.5/200mg NV</td>
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<td>4</td>
<td>*399.96</td>
<td>37.70</td>
<td>Stalevo 200/50/200mg NV</td>
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<td>8797B</td>
<td>levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100</td>
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<td>*312.22</td>
<td>37.70</td>
<td>Stalevo 50/12.5/200mg NV</td>
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<td>9344T</td>
<td>levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100</td>
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<td>4</td>
<td>*325.46</td>
<td>37.70</td>
<td>Stalevo 75/18.75/200mg NV</td>
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**Adamantane derivatives**

**AMANTADINE**

**Restricted benefit**

Parkinson’s disease which is not drug induced

**Note**

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<tr>
<td>3016R</td>
<td>amantadine hydrochloride 100 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>44.64</td>
<td>37.70</td>
<td>Symmetrel 100 NV</td>
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**Dopamine agonists**

**BROMOCRIPTINE**

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson’s disease

**Restricted benefit**

Pathological hyperprolactinaemia where surgery is not indicated

**Restricted benefit**

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
### NERVOUS SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Pathological hyperprolactinaemia where radiotherapy is not indicated</td>
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<tr>
<td></td>
<td>Restricted benefit</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution</td>
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<td></td>
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</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.</td>
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<td>For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.</td>
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<td>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.</td>
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**NERVOUS SYSTEM**

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</table>

**Caution**
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Note**
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**
No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.

**Note**
Continuing Therapy Only:

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

### PRAMIPEXOLE

**Restricted benefit**
Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient’s medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes.

**Caution**
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Note**
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

**Note**
Continuing Therapy Only:

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

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<th>Brand Name and Manufacturer</th>
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<td>3420B NP</td>
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<td>57.24</td>
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<td>5143Q NP</td>
<td>pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets</td>
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<td>ROTIGOTINE</td>
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<td>5</td>
<td>77.59</td>
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<td>2384L</td>
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<td>113.92</td>
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<td><strong>Monoamine oxidase B inhibitors</strong></td>
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<td>1952R</td>
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<td>121.93</td>
<td>37.70</td>
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<td>1973W</td>
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<td>5</td>
<td>53.30</td>
<td>37.70</td>
<td>a Eldepryl</td>
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<td>SELEGILINE</td>
<td><strong>Restricted benefit</strong> Late stage Parkinson’s disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations</td>
<td>8367J</td>
<td>100</td>
<td>2</td>
<td>4</td>
<td>a 282.16</td>
<td>37.70</td>
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<td><strong>Other dopaminergic agents</strong></td>
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**PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

**Phenothiazines with aliphatic side-chain**

CHLORPROMAZINE

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</table>

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised model.

---

**Clinical criteria:**

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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<td>1201F</td>
<td>chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL</td>
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<td>1195X</td>
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<td>..</td>
<td>20.82</td>
<td>21.97</td>
<td>Largactil SW</td>
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**Phenothiazines with piperazine structure**

**FLUPHENAZINE DECANOATE**

**Note**

Shared Care Model:

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

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<td>3098C</td>
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<td>26.72</td>
<td>27.87</td>
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<tr>
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<td>..</td>
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<td>37.70</td>
<td>Modecate BQ</td>
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**TRIFLUOPERAZINE**

**Note**

Shared Care Model:

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

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<th>Brand Name and Manufacturer</th>
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<td>16.85</td>
<td>18.00</td>
<td>Stelazine GH</td>
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<td>2386N</td>
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<td>23.86</td>
<td>25.01</td>
<td>Stelazine GH</td>
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**Phenothiazines with piperidine structure**

**PERICYAZINE**

**Note**

Shared Care Model:

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

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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>15.53</td>
<td>16.68</td>
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<td>3052P</td>
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<td>11.03</td>
<td>12.18</td>
<td>Neulactil SW</td>
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</tbody>
</table>

**Butyrophenone derivatives**

**HALOPERIDOL**

**Note**

Shared Care Model:

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

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<td>2767P</td>
<td>haloperidol 1.5 mg tablet, 100</td>
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<td>11.25</td>
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<td>2763K</td>
<td>haloperidol 2 mg/mL oral liquid, 100 mL</td>
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<td>20.79</td>
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<td>2770T</td>
<td>haloperidol 5 mg tablet, 50</td>
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<td>2761H</td>
<td>haloperidol 500 microgram tablet, 100</td>
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**HALOPERIDOL DECANOATE**
### NERVOUS SYSTEM

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<tr>
<td>2766N</td>
<td>haloperidol (as decanoate) 150 mg/mL injection, 5 x 3 mL ampoules</td>
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<td>51.87</td>
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<td>Haldol decanoate</td>
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<td>2765M</td>
<td>haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials</td>
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<td>30.06</td>
<td>31.21</td>
<td>Haldol decanoate</td>
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**Indole derivatives**

**ZIPRASIDONE**

**Authority required (STREAMLINED)**

1589 Schizophrenia

**Authority required (STREAMLINED)**

3084 Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

**Note**

Shared Care Model:

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

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**Thioxanthene derivatives**

**FLUPENTHIXOL DECANOATE**

**Note**

Shared Care Model:

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

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<td>2257T</td>
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**ZUCLOPENTHIXOL DECANOATE**

**Note**

Shared Care Model:

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

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<td>8097E</td>
<td>zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules</td>
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**Diazepines, oxazepines, thiazepines and oxepines**

**ASENAPINE**

**Authority required (STREAMLINED)**

1589 Schizophrenia

**Authority required (STREAMLINED)**

3935 Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

**Authority required (STREAMLINED)**

3936
**NERVOUS SYSTEM**

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<td>5141N NP</td>
<td>asenapine 10 mg wafer: sublingual, 60 wafers</td>
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**Maintenance treatment, as monotherapy, of bipolar I disorder**

**Note**

*Shared Care Model:*

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

**OLANZAPINE**

**Authority required [STREAMLINED]**

**1589**

Schizophrenia

**Authority required [STREAMLINED]**

**2044**

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

<table>
<thead>
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<th>Name, Restriction, Manner of Administration and Form</th>
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**OLANZAPINE**

**Authority required [STREAMLINED]**

**1589**

Schizophrenia

**Authority required [STREAMLINED]**

**2044**

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

<table>
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**OLANZAPINE**
### NERVOUS SYSTEM

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<td>olanzapine 10 mg wafer, 28</td>
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</tbody>
</table>

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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### NERVOUS SYSTEM

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</table>

#### OLANZAPINE

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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#### OLANZAPINE

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1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note**

Shared Care Model:
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#### OLANZAPINE

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

<table>
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#### OLANZAPINE

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note**
## NERVOUS SYSTEM

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**OLANZAPINE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

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**OLANZAPINE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

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**OLANZAPINE**

**Authority required (STREAMLINED)**

4304

Schizophrenia

**Caution**
Monitor for post-injection syndrome for at least two hours after each injection.

**Note**
Special Pricing Arrangements apply.

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

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**OLANZAPINE**

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**Note**
Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

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**OLANZAPINE**

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

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**QUETIAPINE**

**Authority required (STREAMLINED)**

4391
Schizophrenia

**Clinical criteria:**

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

4396
Acute mania

**Clinical criteria:**

The condition must be associated with bipolar I disorder,

AND

The treatment must be as monotherapy,

AND

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

4385
Bipolar I disorder

**Clinical criteria:**

The treatment must be maintenance therapy,

AND

The treatment must be for dose titration purposes.

**Note**
### NERVOUS SYSTEM

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### Benzamides

**AMISULPRIDE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Note**

Shared Care Model:

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

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8736T NP

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8596K NP

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### Other antipsychotics

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

**Note**

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

**Shared Care Model**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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| PALIPERIDONE | **Authority required (STREAMLINED)** | | | | | |
| 4246  | Schizophrenia | | | | | |
| **Note** | | | | | | |
| **Shared Care Model:** | | | | | | |
| For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | |
| 10224D | aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack | 1 5 | ... | 324.91 | 37.70 | BQ |
| 10219W | aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack | 1 5 | ... | 399.95 | 37.70 | BQ |

| PALIPERIDONE | **Authority required (STREAMLINED)** | | | | | |
| 4246  | Schizophrenia | | | | | |
| **Note** | | | | | | |
| **Shared Care Model:** | | | | | | |
| For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | |
| 5107T | paliperidone 100 mg injection: modified release, 1 syringe | 1 5 | ... | 441.03 | 37.70 | BQ |
| 5109X | paliperidone 150 mg injection: modified release, 1 syringe | 1 5 | ... | 441.03 | 37.70 | BQ |
| 5100K | paliperidone 25 mg injection: modified release, 1 syringe | 1 5 | ... | 149.97 | 37.70 | BQ |
| 9140C | paliperidone 3 mg tablet: modified release, 28 tablets | 1 5 | ... | 79.93 | 37.70 | BQ |
| 5102M | paliperidone 50 mg injection: modified release, 1 syringe | 1 5 | ... | 285.14 | 37.70 | BQ |
| 9141D | paliperidone 6 mg tablet: modified release, 28 tablets | 1 5 | ... | 154.60 | 37.70 | BQ |
| 5103N | paliperidone 75 mg injection: modified release, 1 syringe | 1 5 | ... | 363.48 | 37.70 | BQ |
| 9142E | paliperidone 9 mg tablet: modified release, 28 tablets | 1 5 | ... | 226.35 | 37.70 | BQ |

| RISPERIDONE | **Authority required (STREAMLINED)** | | | | | |
| 1589  | Schizophrenia | | | | | |
| **Authority required (STREAMLINED)** | | | | | | |
| 2272  | Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder | | | | | |
### NERVOUS SYSTEM

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**Note**

Shared Care Model:

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

Authority required (STREAMLINED)

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Caution

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note

Shared Care Model:

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

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders

### RISPERIDONE

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

3841

Maintenance treatment, in combination with lithium or sodium valproate, of treatment refractory bipolar I disorder

**Note**

Shared Care Model:

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

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### RISPERIDONE

**Authority required (STREAMLINED)**

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

**Authority required (STREAMLINED)**

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10
Caution
In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note
For item codes 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

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

RISPERIDONE
Authority required (STREAMLINED)
1589
Schizophrenia

Note
For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

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

RISPERIDONE
Authority required (STREAMLINED)
1589
Schizophrenia

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

**Benzodiazepine derivatives**

#### ALPRAZOLAM

**Authority required**

Panic disorder where other treatments have failed or are inappropriate

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<td>12.51</td>
<td>13.66</td>
<td></td>
<td>Alprax 0.5 QA</td>
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<td>Kalma 0.5 AF</td>
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</tbody>
</table>

#### DIAZEPAM

**Authority required**

Chronic spasticity

Population criteria:
Patient must be under 18 years of age.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2669L</td>
<td>diazepam 1 mg/mL oral liquid, 100 mL</td>
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<td>43.12</td>
<td>37.70</td>
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<td>Diazepam Elixir ON</td>
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</tbody>
</table>

#### DIAZEPAM

**Note**

Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months’ treatment (i.e. one month’s treatment with five repeats) may be requested.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>9.07</td>
<td>a Antenex 2 AF</td>
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### NERVOUS SYSTEM

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### OXAZEPAM

**Note**
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of oxazepam below.

<table>
<thead>
<tr>
<th>Code</th>
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<td>9.15</td>
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</table>

### OXAZEPAM

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

**Authority required**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

<table>
<thead>
<tr>
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### OXAZEPAM

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### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

### NITRAZEPAM

**Note**
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of nitrazepam below.

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<th>Code</th>
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<td>9.50</td>
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### NITRAZEPAM
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<td>Temaze AF</td>
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<td></td>
<td>$4.00</td>
<td>$11.69</td>
<td>Normison QA</td>
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</tbody>
</table>

**Authority required**

Myoclonic epilepsy

Malignant neoplasia (late stage)

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

Continuing Therapy Only:

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

**Authority required**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

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For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

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### NERVOUS SYSTEM

### PSYCHOANALEPTICS

#### ANTIDEPRESSANTS

**Non-selective monoamine reuptake inhibitors**

#### AMITRIPTYLINE

**Note**
Continuing Therapy Only:

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<table>
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<td>Chem mart Amtriptyline CH</td>
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<td></td>
<td></td>
<td>Endep 50 AF</td>
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</tbody>
</table>

#### CLOMIPRAMINE

**Restricted benefit**
Cataplexy associated with narcolepsy

**Restricted benefit**
Obsessive-compulsive disorder

**Restricted benefit**
Phobic disorders in adults

**Note**
Continuing Therapy Only:

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

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<tr>
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<td>Terry White Chemists Clomipramine TW</td>
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</tbody>
</table>

#### DOXEPIN

**Note**
Continuing Therapy Only:

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

<table>
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#### DOXEPIN

**Note**
Continuing Therapy Only:
## NERVOUS SYSTEM

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

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### NERVOUS SYSTEM

**ESCITALOPRAM**

**Restricted benefit**

Major depressive disorders

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ESCITALOPRAM

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria.

AND

Patient must not have responded to non-pharmacological therapy.

AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)
NERVOUS SYSTEM

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
AND
Patient must not have responded to non-pharmacological therapy,
AND
Patient must have been assessed by a psychiatrist.

Restricted benefit
Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
AND
Patient must not have responded to non-pharmacological therapy,
AND
Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit
Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
AND
Patient must not have responded to non-pharmacological therapy,
AND
Patient must have been assessed by a psychiatrist.

ESCITALOPRAM

Restricted benefit
Major depressive disorders

Restricted benefit
Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
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Patient must not have responded to non-pharmacological therapy,
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Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit
Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
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Patient must not have responded to non-pharmacological therapy,
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Patient must have been assessed by a psychiatrist.

Restricted benefit
Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,
AND
Patient must not have responded to non-pharmacological therapy,

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Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**
Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,

AND
Patient must not have responded to non-pharmacological therapy,

AND
Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

Max. Qty (Packs) 5
No. of Rpts ..
Premium Price for Max. Qty $36.63
Maximum Recordable Value for Safety Net $37.70
Brand Name and Manufacturer Lexapro LU

**FLUOXETINE**

**Restricted benefit**
Major depressive disorders

**Restricted benefit**
Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

Max. Qty (Packs) 1
No. of Rpts 5
Premium Price for Max. Qty $12.35
Maximum Recordable Value for Safety Net $13.50
Brand Name and ManufacturerAuscap Aspen QA

**fluoxetine 50 mg tablet, 30**

Max. Qty (Packs) 1
No. of Rpts 5
Premium Price for Max. Qty $14.14
Maximum Recordable Value for Safety Net $15.29
Brand Name and Manufacturer APO-Fluoxetine TX

**FLUOXAMINE**

**Restricted benefit**
Major depressive disorders

**Restricted benefit**
Obsessive-compulsive disorder

**fluvoxamine maleate 100 mg tablet, 30**

Max. Qty (Packs) 1
No. of Rpts 5
Premium Price for Max. Qty $17.95
Maximum Recordable Value for Safety Net $19.10
Brand Name and Manufacturer Faverin 100 QA

**fluvoxamine maleate 50 mg tablet, 30**

Max. Qty (Packs) 1
No. of Rpts 5
Premium Price for Max. Qty $14.14
Maximum Recordable Value for Safety Net $15.29
Brand Name and Manufacturer Faverin 50 QA
**NERVOUS SYSTEM**

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<td>a Terry White Chemists Sertraline</td>
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**Note**
Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution.
### NERVOUS SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>sertraline 50 mg tablet, 30</td>
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<td>9.55</td>
<td>10.70</td>
<td>(^a) Auro-Sertraline 100 DO</td>
<td>(^a) Eleva 100 AF</td>
<td>(^a) Sertraline Actavis UA</td>
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**Monoamine oxidase inhibitors, non-selective**

| PHENELZINE | Restricted benefit | Depression where all other anti-depressant therapy has failed or is inappropriate | 2856H | phenelzine 15 mg tablet, 100 | 1 1 .. | 100.44 | 37.70 | Nardil LM |

**TRANYLCYPROMINE**

| Caution | This drug is an irreversible monoamine oxidase inhibitor. | 2444P | tranylcypromine 10 mg tablet, 50 | 1 2 .. | 58.66 | 37.70 | Parnate GH |

**Monoamine oxidase A inhibitors**

| MOCLOBEMIDE | Restricted benefit | Major depressive disorders | 1900B | moclobemide 150 mg tablet, 60 | 1 5 .. | 13.14 | 14.29 | Amira 150 AF | \(^a\) Chem mart CH | \(^a\) Moclobemide CH | \(^a\) Clobemix GN | \(^a\) GenRx Moclobemide GX | \(^a\) Moclobemide AN EA | \(^a\) Moclobemide Sandoz SZ | \(^a\) Mohexal HX | \(^a\) Terry White Chemists Moclobemide TW | \(^a\) Aurorix HM |
| 8003F | moclobemide 300 mg tablet, 60 | 1 5 .. | 19.04 | 20.19 | \(^a\) Amira 300 AF | \(^a\) Chem mart CH | \(^a\) Moclobemide CH | \(^a\) Clobemix GN |
NERVOUS SYSTEM

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Other antidepressants

**DESVENLAFAXINE**

**Restricted benefit**
Major depressive disorders

**Note**
Continuing Therapy Only:
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**Note**
Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note**
Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**DULOXETINE**

**Restricted benefit**
Major depressive disorders

**Note**
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## NERVOUS SYSTEM

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### LITHIUM CARBONATE

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</table>

### MIANSERIN

**Restricted benefit**

**Severe depression**

**Caution**
Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note**
Continuing Therapy Only:

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### MIRTAZAPINE

**Restricted benefit**

**Major depressive disorders**

**Note**
Continuing Therapy Only:

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### NERVOUS SYSTEM

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8302Y  | venlafaxine 150 mg capsule: modified release, 28 capsules | 1                | 5           | ..        | 18.81                          | 19.96                                       | Altven FZ                   |
|        |                                                     |                  |             |           |                               |                                             | APO-Venlafaxine XR TX        |
|        |                                                     |                  |             |           |                               |                                             | Blooms the Chemist Venlafaxine XR IB |
|        |                                                     |                  |             |           |                               |                                             | Chem mart Venlafaxine XR CH  |
|        |                                                     |                  |             |           |                               |                                             | Efexor-XR PF                 |
|        |                                                     |                  |             |           |                               |                                             | Elaxine SR 150 ZP            |
|        |                                                     |                  |             |           |                               |                                             | Enlafax-XR AF                |
|        |                                                     |                  |             |           |                               |                                             | Terry White Chemists TW      |
|        |                                                     |                  |             |           |                               |                                             | Venlafaxine XR               |
|        |                                                     |                  |             |           |                               |                                             | Venlafaxine Actavis XR UA    |
|        |                                                     |                  |             |           |                               |                                             | Venlafaxine AN SR EA        |
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</table>
| 8868R   | venlafaxine 37.5 mg capsule: modified release, 28 capsules | 1                | ..          | 12.36                    | 13.51                         |                                           | a. Venlafaxine generichealth XR GQ  
          |                                                      |                  |              |                          |                               |                                           | a. Venlafaxine Sandoz XR SZ  
          |                                                      |                  |              |                          |                               |                                           | a. Venlafaxine SR SCP 150 CR  
          |                                                      |                  |              |                          |                               |                                           | a. Venla RBX RA  
          |                                                      |                  |              |                          |                               |                                           | a. Venlexor XR GN  
          |                                                      |                  |              |                          |                               |                                           | a. Altven FZ  
          |                                                      |                  |              |                          |                               |                                           | a. Efexor-XR PF  
          |                                                      |                  |              |                          |                               |                                           | a. Elaxine SR 37.5 ZP  
          |                                                      |                  |              |                          |                               |                                           | a. Venlafaxine Actavis XR UA  
          |                                                      |                  |              |                          |                               |                                           | a. Venlafaxine AN SR EA  
          |                                                      |                  |              |                          |                               |                                           | a. Altven FZ |
| 8301X   | venlafaxine 75 mg capsule: modified release, 28 capsules | 1                | 5           | 16.65                    | 17.80                         |                                           | a. APO-Venlafaxine XR TX  
          |                                                      |                  |              |                          |                               |                                           | a. Blooms the Chemist Venlafaxine XR IB  
          |                                                      |                  |              |                          |                               |                                           | a. Chem mart Venlafaxine XR CH  
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          |                                                      |                  |              |                          |                               |                                           | a. Venlexor XR GN |

PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

Centrally acting sympathomimetics

ATOMOXETINE

Authority required (STREAMLINED) 4591

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Clinical criteria:
The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, AND

Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR

Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR

Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR

Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously).

Population criteria:
Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED) 4578

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug.

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

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### DEXAMPHETAMINE

**Authority required**
- Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

**Note**
- Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

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

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### METHYLPHENIDATE

**Authority required**
- Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

**Note**
- Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**Note**
- Continuing Therapy Only:
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### METHYLPHENIDATE

**Authority required**
- Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

**Note**
- Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**Note**
- Continuing Therapy Only:
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NERVOUS SYSTEM

METHYLPHENIDATE

**Authority required**

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**Note**

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MODAFINIL

**Authority required**

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:

(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or

(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

(i) a definite history of cataplexy;

or

a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;

or

an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and

(ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Authority required**

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug.

**Note**

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

Written applications for authority to prescribe modafinil should be forwarded to:
NERVOUS SYSTEM

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<td>Further prescribing information is on the Medicare Australia website at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a>.</td>
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**Note**

Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

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ANTI-DEMENTIA DRUGS

Anticholinesterases

DONEPEZIL

**Authority required (STREAMLINED)**

4219

Mild to moderately severe Alzheimer disease

**Treatment Phase: Continuing**

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug,
- **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment,
- **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

- Patient’s quality of life including but not limited to level of independence and happiness;
- Patient’s cognitive function including but not limited to memory, recognition and interest in environment;
- Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

**Continuing Therapy Only:**

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

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|        |                                                      |                  |             |           |                               |                                   | Aricept P                      |
DONEPEZIL

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down’s syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.

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Note

Continuing Therapy Only:

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

GALANTAMINE

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient’s quality of life including but not limited to level of independence and happiness;

Patient’s cognitive function including but not limited to memory, recognition and interest in environment;

Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.
### GALANTAMINE

**Authority required**

Mild to moderately severe Alzheimer disease  
Treatment Phase: Initial

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,  
AND  
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),  
AND  
The treatment must be the sole PBS-subsidised therapy for this condition.  
The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.  
The application must be made in writing, but initial supply may be sought by telephone.  
For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.  
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease  
Treatment Phase: Initial

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,  
AND  
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),  
AND  
The treatment must be the sole PBS-subsidised therapy for this condition.  
A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.  
Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.  
Patients who qualify under this criterion are from 1 or more of the following groups:  
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;  
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;  
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
**NERVOUS SYSTEM**

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**RIVASTIGMINE**

**Authority required (STREAMLINED)**

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND

Patient must demonstrate a clinically meaningful response to the initial treatment, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatement should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

- Patient’s quality of life including but not limited to level of independence and happiness;
- Patient’s cognitive function including but not limited to memory, recognition and interest in environment;
- Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

Continuing Therapy Only:

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

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### RIVASTIGMINE

**Authority required**

Mild to moderately severe Alzheimer disease

**Treatment Phase:** Initial

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

**Treatment Phase:** Initial

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4. Intellectual (developmental or acquired) disability, eg Down's syndrome;
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

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NERVOUS SYSTEM

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MEMANTINE
Authority required
Moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:
Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, AND
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
The treatment must be the sole PBS-subsidised therapy for this condition.
The application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

Authority required
Moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:
Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
The treatment must be the sole PBS-subsidised therapy for this condition.
A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.
Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.
Patients who qualify under this criterion are from 1 or more of the following groups:
1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4) Intellectual (developmental or acquired) disability, eg Down’s syndrome;
5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.
The application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial

Other anti-dementia drugs
MEMANTINE  
Authority required (STREAMLINED)  
4214  
Moderately severe Alzheimer disease  
Treatment Phase: Continuing  
Clinical criteria:  
Patient must have received six months of sole PBS-subsidised initial therapy with this drug,  
AND  
Patient must demonstrate a clinically meaningful response to the initial treatment,  
AND  
The treatment must be the sole PBS-subsidised therapy for this condition.  
Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.  
Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.  
Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.  
Clinically meaningful response to treatment is demonstrated in the following areas:  
Patient’s quality of life including but not limited to level of independence and happiness;  
Patient’s cognitive function including but not limited to memory, recognition and interest in environment;  
Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.  

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

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Note  
Continuing Therapy Only:  
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

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

### PARASYMPATHOMIMETICS

#### Anticholinesterases

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<tr>
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<td>PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50</td>
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<td>23.34</td>
<td>24.49</td>
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<tr>
<td>2608G</td>
<td>pyridostigmine bromide 180 mg tablet: modified release, 50 tablets</td>
<td>2</td>
<td>5</td>
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<td>37.70</td>
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#### Choline esters

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<td>33.87</td>
<td>35.02</td>
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### DRUGS USED IN ADDICTIVE DISORDERS

#### Drugs used in nicotine dependence

**BUPROPION**

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the authority application.

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the authority application.

**Note**

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>8465M</td>
<td>bupropion hydrochloride 150 mg tablet: modified release, 30 tablets</td>
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<td>..</td>
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<td>63.34</td>
<td>37.70</td>
<td>Prexaton GN</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>0.80</td>
<td>64.14</td>
<td>Zyban AS</td>
</tr>
</tbody>
</table>

**BUPROPION**

**Authority required**

Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.

**Note**

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

<table>
<thead>
<tr>
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**NICOTINE**

**Authority required (STREAMLINED)**

4348
Nicotine dependence

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

**AND**

Patient must have indicated they are ready to cease smoking,

**AND**

Patient must have entered a comprehensive support and counselling program,
AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)**

4307

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking,

AND

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written,

AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Note

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

Note

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

5572G

nicotine 14 mg/24 hours patch, 28

1

2

55.56

37.70

Nicotinell Step 2

NC

3414Q

nicotine 21 mg/24 hours patch, 28

1

2

55.56

37.70

Nicotinell Step 1

NC

5573H

nicotine 7 mg/24 hours patch, 28

1

2

55.56

37.70

Nicotinell Step 3

NC

NICOTINE

**Authority required (STREAMLINED)**

4344

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

Note

Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note

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

Note

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

**Authority required (STREAMLINED)**

4348

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking,

AND

Patient must have entered a comprehensive support and counselling program,

AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Note

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

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>Patient must have indicated they are ready to cease smoking.</td>
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<td>Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written,</td>
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<td></td>
<td>Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.</td>
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<td>Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</td>
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<td>Patient must be an Aboriginal or a Torres Strait Islander person.</td>
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<td>Note</td>
<td>Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.</td>
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<td>Benefit is improved if used in conjunction with a comprehensive support and counselling program.</td>
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<td>Treatment Phase: Completion of a short-term (24 weeks) course of treatment</td>
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<td>The treatment must be as an aid to achieving abstinence from smoking.</td>
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<td>AND</td>
<td>The treatment must be the sole PBS-subsidised therapy for this condition,</td>
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<tr>
<td></td>
<td>AND</td>
<td>Patient must have previously been issued with an authority prescription for this drug during this current course of treatment,</td>
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<tr>
<td></td>
<td>AND</td>
<td>Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.</td>
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**Varenicline**

**Nervous System**

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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>37.70</td>
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**Nervous System**

**Code**

**Name, Restriction, Manner of Administration and Form**

**Max. Qty (Packs)**

**No. of Rpts**

**Premium $**

**Dispensed Price for Max. Qty $**

**Maximum Recordable Value for Safety Net $**

**Brand Name and Manufacturer**

**Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.**

**Note**

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note**

A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note**

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

**Note**

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

---

**Varenicline**

**Authority required**

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

The treatment must be as an aid to achieving abstinence from smoking,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been issued with an authority prescription for this drug during this current course of treatment.

**Treatment criteria:**

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**Note**

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note**

A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note**

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

**Note**

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

---

**Varenicline**

**Authority required**

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

The treatment must be as an aid to achieving abstinence from smoking,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking.

**Treatment criteria:**

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time the Authority application is requested.

Details of the support and counselling program must be documented in the patient’s medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**Note**

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note**

The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note**
NERVOUS SYSTEM

A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

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

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

9128K

NP

varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53

‡1

.. 103.46 37.70 Champix PF

Drugs used in alcohol dependence

ACAMPROSATE
Authority required (STREAMLINED)

2665

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence

Note
No applications for increased maximum quantities and/or repeats will be authorised.

8357W

NP

acamprosate calcium 333 mg tablet: enteric, 180 tablets

1 1 .. 166.92 37.70 Campral AF

NALTREXONE
Authority required

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence

Caution
Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

8370M

NP

naltrexone hydrochloride 50 mg tablet, 30

1 1 .. 136.01 37.70 a Naltrexone GH GQ

a

ReVia BQ

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

DIMETHYL FUMARATE
Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

The treatment must be as monotherapy,

AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

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

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

Note
Special Pricing Arrangements apply.

2896K

dimethyl fumarate 120 mg capsule, 14

1 .. .. 491.31 37.70 Tecfidera BD

DIMETHYL FUMARATE
**NERVOUS SYSTEM**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<td></td>
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<tr>
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<td>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR</td>
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<td></td>
<td>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND</td>
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<td></td>
<td>Patient must have previously been issued with an authority prescription for this drug; OR</td>
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<td>Patient must have been receiving treatment with this drug prior to 1 December 2013, AND</td>
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<tr>
<td></td>
<td>Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application. Note: Special Pricing Arrangements apply.</td>
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<td>37.70</td>
<td>Tecfidera BD</td>
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<td>DIMETHYL FUMARATE</td>
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<tr>
<td></td>
<td>Patient must have previously been issued with an authority prescription for this drug; OR</td>
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<tr>
<td></td>
<td>Patient must have been receiving treatment with this drug prior to 1 December 2013, AND</td>
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<tr>
<td></td>
<td>Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application. Note: Special Pricing Arrangements apply.</td>
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<td>2966D</td>
<td>dimethyl fumarate 240 mg capsule, 56</td>
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<td>1880.00</td>
<td>37.70</td>
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<td></td>
<td>RILUZOLE</td>
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<tr>
<td></td>
<td>Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who: (1) are ambulatory, and</td>
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<tr>
<td></td>
<td>(a) have not undergone tracheostomy, and (b) have not experienced respiratory failure; OR (2) are not ambulatory, and</td>
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</tbody>
</table>
NERVOUS SYSTEM

(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure, and
(c) are either able to use upper limbs or able to swallow.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application

**Authority required**
Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:
(1) are ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure; OR
(2) are not ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure, and
(c) are either able to use upper limbs or able to swallow

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

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<tr>
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<td>8664B</td>
<td>riluzole 50 mg tablet, 56</td>
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<td>37.70</td>
<td>a APO-Riluzole TX</td>
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<td>a Pharmacor Riluzole CR</td>
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<td>a Rilutek SW</td>
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<td>a Riluzole Sandoz SZ</td>
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**TETRABENAZINE**

**Authority required (STREAMLINED)**

1161
Hyperkinetic extrapyramidal disorders

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

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<td>1330B</td>
<td>tetrabenazine 25 mg tablet, 112</td>
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<td>364.25</td>
<td>37.70</td>
<td>iNova Pharmaceuticals (Australia) Pty Ltd IA</td>
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</table>
### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

#### ANTIPROTOZOALS

**Agents Against Amoebiasis and Other Protozoal Diseases**

*Other agents against amoebiasis and other protozoal diseases*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8300W</td>
<td>atovaquone 750 mg/5 mL oral liquid, 210 mL ‡1</td>
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<td>1034.91</td>
<td>37.70</td>
<td>37.70</td>
<td>Wellvone AS</td>
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<td>1966L</td>
<td>pyrimethamine 25 mg tablet, 50</td>
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<td>17.87</td>
<td>17.87</td>
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#### ANTIMALARIALS

**Biguanides**

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<td>9439T</td>
<td>atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12</td>
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<td>67.34</td>
<td>37.70</td>
<td>37.70</td>
<td>Malarone GK</td>
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</table>

#### Methanolquinolines

**Quinine**

Authority required (STREAMLINED)

<table>
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<th>Code</th>
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<td>1975Y</td>
<td>quinine sulfate 300 mg tablet, 50</td>
<td>1</td>
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<td>14.48</td>
<td>15.63</td>
<td>15.63</td>
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</table>

**Artemisinin and derivatives, combinations**

**Artemether + Lumefantrine**

Authority required

Treatment of suspected or confirmed malaria due to Plasmodium falciparum

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>9498X</td>
<td>artemether 20 mg + lumefantrine 120 mg tablet, 24</td>
<td>1</td>
<td>..</td>
<td>97.24</td>
<td>37.70</td>
<td>37.70</td>
<td>Riamet NV</td>
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</table>
### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

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</thead>
<tbody>
<tr>
<td>lumefantrine</td>
<td>Note: Artemether with lumezantrine is not PBS-subsidised for prophylaxis of malaria.</td>
<td>5296R</td>
<td>artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18</td>
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### ANTHELMINTICS

#### ANTITREMATODALS

**Quinoline derivatives and related substances**

**PRAZIQUANTEL**

*Authority required (STREAMLINED)*

3147

Schistosomiasis

<table>
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<tr>
<th>Code</th>
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<td>9447F</td>
<td>praziquantel 600 mg tablet, 8</td>
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#### ANTINEMATODAL AGENTS

**Benzimidazole derivatives**

**ALBENDAZOLE**

*Authority required (STREAMLINED)*

1525

Treatment of tapeworm infestation

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>1</td>
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<td>33.44</td>
<td>34.59</td>
<td>Zentel</td>
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**ALBENDAZOLE**

*Authority required (STREAMLINED)*

2446

Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person

*Authority required (STREAMLINED)*

1388

Strongyloidiasis

*Authority required (STREAMLINED)*

3241

Treatment of hookworm infestation

<table>
<thead>
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<th>Code</th>
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<td>33.44</td>
<td>34.59</td>
<td>Zentel</td>
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**ALBENDAZOLE**

*Authority required (STREAMLINED)*

1496

For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used

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<th>Code</th>
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<td>8459F</td>
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#### Tetrahydropyrimidine derivatives

**PYRANTEL**

3047J

pyrantel 125 mg tablet, 6

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<tr>
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<td>..</td>
<td>..</td>
<td>14.94</td>
<td>16.09</td>
<td>Anthel 125</td>
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3048K

pyrantel 250 mg tablet, 6

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<td>3048K</td>
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<td>23.11</td>
<td>24.26</td>
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#### Avermectines

**IVERMECTIN**

*Authority required (STREAMLINED)*

4328

Strongyloidiasis

*Authority required (STREAMLINED)*

4565

Crusted (Norwegian) scabies

Clinical criteria:
<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>4566</td>
<td>Human sarcoptic scabies</td>
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<td>2868Y NP</td>
<td>ivermectin 3 mg tablet, 4</td>
<td>2</td>
<td>2</td>
<td></td>
<td>*54.54</td>
<td>37.70</td>
<td>Stromectol MK</td>
</tr>
<tr>
<td>8359Y NP</td>
<td>ivermectin 3 mg tablet, 4</td>
<td>1</td>
<td>..</td>
<td></td>
<td>31.65</td>
<td>32.80</td>
<td>Stromectol MK</td>
</tr>
</tbody>
</table>

**ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS**

**ECTOPARASITICIDES, INCL. SCABICIDES**

*Pyrethrines, incl. synthetic compounds*

**PERMETHRIN**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3054R NP</td>
<td>permethrin 5% cream, 30 g</td>
<td>‡1</td>
<td>1</td>
<td></td>
<td>17.11</td>
<td>18.26</td>
<td>Lyclear JT</td>
</tr>
</tbody>
</table>
## RESPIRATORY SYSTEM

### NASAL PREPARATIONS

**DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE**

**Other nasal preparations**

**MUPIROCIN**

**Authority required (STREAMLINED)**

3136

Nasal colonisation with *Staphylococcus aureus* in an Aboriginal or a Torres Strait Islander person

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9440W</td>
<td>mupirocin 2% (20 mg/g) ointment, 3 g</td>
<td>‡1</td>
<td>..</td>
<td>20.97</td>
<td>22.12</td>
<td>Bactroban</td>
</tr>
</tbody>
</table>

### DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

#### ADRENERGICS, INHALANTS

**Selective beta-2-adrenoreceptor agonists**

**EFROMOTEROL**

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8136F</td>
<td>eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules</td>
<td>1</td>
<td>5</td>
<td>37.67</td>
<td>37.70</td>
<td>Foradile</td>
</tr>
<tr>
<td>8240Q</td>
<td>eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1</td>
<td>5</td>
<td>36.78</td>
<td>37.70</td>
<td>Oxis Turbuhaler</td>
</tr>
<tr>
<td>8239P</td>
<td>eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1</td>
<td>5</td>
<td>26.72</td>
<td>27.87</td>
<td>Oxis Turbuhaler</td>
</tr>
</tbody>
</table>

**INDACATEROL**

**Restricted benefit**

Chronic obstructive pulmonary disease

**Note**

Indacaterol is not PBS-subsidised for the treatment of asthma.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5134F</td>
<td>indacaterol 150 microgram inhalation: powder for, 30 capsules</td>
<td>1</td>
<td>5</td>
<td>62.73</td>
<td>37.70</td>
<td>Onbrez</td>
</tr>
<tr>
<td>5137J</td>
<td>indacaterol 300 microgram inhalation: powder for, 30 capsules</td>
<td>1</td>
<td>5</td>
<td>62.73</td>
<td>37.70</td>
<td>Onbrez</td>
</tr>
</tbody>
</table>

**SALBUTAMOL**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8288F</td>
<td>salbutamol 100 microgram/actuation inhalation: pressurised, 200</td>
<td>2</td>
<td>5</td>
<td>*14.14</td>
<td>15.29</td>
<td>APO-Salbutamol Inhaler TX</td>
</tr>
<tr>
<td>10143W</td>
<td>salbutamol 200 microgram inhalation: powder for, 128 capsules</td>
<td>2</td>
<td>4</td>
<td>*2.34</td>
<td>*16.48</td>
<td>APO-Salbutamol Inhaler TX</td>
</tr>
</tbody>
</table>

**SALBUTAMOL**

**Restricted benefit**

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

**Restricted benefit**

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000G</td>
<td>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>2</td>
<td>5</td>
<td>*15.96</td>
<td>17.11</td>
<td>APO-Salbutamol TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>APO-Salbutamol TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>APO-Salbutamol TX</td>
</tr>
</tbody>
</table>

### Notes

- The dispensed price for the maximum quantity is provided along with the premium value for safety net.
- The maximum recordable value for safety net is also indicated.
- Brand names and manufacturers are listed for each product.
- Additional restrictions and conditions may apply as mentioned in the notes.

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### RESPIRATORY SYSTEM

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>GenRx SalbutamolGX</td>
</tr>
<tr>
<td>Pharmacor SalbutamolCR</td>
</tr>
<tr>
<td>Salbutamol ActisUA</td>
</tr>
<tr>
<td>Salbutamol-GAGN</td>
</tr>
<tr>
<td>Salbutamol SandozSZ</td>
</tr>
<tr>
<td>APO-SalbutamolTX</td>
</tr>
<tr>
<td>Asmol 5 uni-doseAF</td>
</tr>
<tr>
<td>Butamol 5QA</td>
</tr>
<tr>
<td>Pharmacor Salbutamol5CR</td>
</tr>
<tr>
<td>Salbutamol ActisUA</td>
</tr>
<tr>
<td>Salbutamol-GAGN</td>
</tr>
<tr>
<td>Salbutamol SandozSZ</td>
</tr>
<tr>
<td>Ventolin NebulesSK</td>
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</tbody>
</table>

### SALBUTAMOL

**Restricted benefit**

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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<tbody>
<tr>
<td>2001H</td>
<td>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>1.20</td>
<td>17.16</td>
</tr>
<tr>
<td>8354Q</td>
<td>salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>38.94</td>
<td>37.70</td>
</tr>
</tbody>
</table>

### SALMETEROL

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>8141L</td>
<td>salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>37.67</td>
<td>37.70</td>
</tr>
<tr>
<td>2817G</td>
<td>terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>18.20</td>
<td>19.35</td>
</tr>
</tbody>
</table>

### TERBUTALINE

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>10015D</td>
<td>budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>59.10</td>
<td>37.70</td>
</tr>
<tr>
<td>10024N</td>
<td>budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>54.80</td>
<td>37.70</td>
</tr>
</tbody>
</table>

### Adrenergics and other drugs for obstructive airway diseases

### BUDESONIDE + EFORMOTEROL

**Restricted benefit**

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

Patient must be aged 12 years or over.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>10015D</td>
<td>budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>59.10</td>
<td>37.70</td>
</tr>
<tr>
<td>10024N</td>
<td>budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>54.80</td>
<td>37.70</td>
</tr>
</tbody>
</table>
Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

Patient must be aged 12 years or over.

BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

Note

Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,

AND

The treatment must be for symptomatic treatment.

Note

Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note

This product is not indicated for the initiation of bronchodilator therapy in COPD.
**FLUTICASONE + EFORMOTEROL**

**Restricted benefit**  
Asthma

**Clinical criteria:**  
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**  
Patient must be aged 12 years or over.

**Note**  
Flutiform is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Note**  
Flutiform is not indicated nor PBS-subsidised for bronchodilator therapy in COPD.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8750M</td>
<td>budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations</td>
<td>‡1 5 ..</td>
<td>89.37</td>
<td>37.70</td>
<td>Symbicort Turbuhaler 400/12</td>
<td>AP</td>
</tr>
<tr>
<td>10007Q</td>
<td>fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5 ..</td>
<td>53.03</td>
<td>37.70</td>
<td>flutiform 125/5</td>
<td>MF</td>
</tr>
<tr>
<td>10008R</td>
<td>fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5 ..</td>
<td>73.01</td>
<td>37.70</td>
<td>flutiform 250/10</td>
<td>MF</td>
</tr>
<tr>
<td>2827T</td>
<td>fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5 ..</td>
<td>43.18</td>
<td>37.70</td>
<td>flutiform 50/5</td>
<td>MF</td>
</tr>
</tbody>
</table>

**FLUTICASONE + SALMETEROL**

**Restricted benefit**  
Asthma

**Clinical criteria:**  
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**AND**  
Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.

**Note**  
Seretide Accuhaler 100/50 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Note**  
Seretide Accuhaler 100/50 is not indicated nor PBS-subsidised for bronchodilator therapy in COPD.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium Price for Max. Qty $</th>
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<tbody>
<tr>
<td>8430Q</td>
<td>fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1 5 ..</td>
<td>47.54</td>
<td>37.70</td>
<td>Seretide Accuhaler 100/50</td>
<td>GK</td>
</tr>
</tbody>
</table>
### FLUTICASONE + SALMETEROL

#### Restricted benefit

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,

**AND**

Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.

**Clinical criteria:**

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

**AND**

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,

**AND**

The treatment must be for symptomatic treatment.

**Note**

Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note**

This product is not indicated for the initiation of bronchodilator therapy in COPD.

### FLUTICASONE + VILANTEROL

#### Restricted benefit

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

Patient must be aged 12 years or over.

**Note**

This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

### Table

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8518H</td>
<td>fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td>55.49</td>
<td>37.70</td>
<td>Seretide MDI 125/25</td>
<td>GK</td>
</tr>
<tr>
<td>8431R</td>
<td>fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td>55.49</td>
<td>37.70</td>
<td>Seretide Accuhaler 250/50</td>
<td>GK</td>
</tr>
<tr>
<td>8517G</td>
<td>fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td>47.54</td>
<td>37.70</td>
<td>Seretide MDI 50/25</td>
<td>GK</td>
</tr>
<tr>
<td>8519J</td>
<td>fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td>72.63</td>
<td>37.70</td>
<td>Seretide MDI 250/25</td>
<td>GK</td>
</tr>
<tr>
<td>8432T</td>
<td>fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td>72.63</td>
<td>37.70</td>
<td>Seretide Accuhaler 500/50</td>
<td>GK</td>
</tr>
</tbody>
</table>
Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.

AND

The treatment must be for symptomatic treatment.

**Note**

Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note**

This product is not indicated for the initiation of bronchodilator therapy in COPD.

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<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>10199T</td>
<td>fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations</td>
<td>‡1 5 ..</td>
<td>56.29</td>
<td>37.70</td>
<td>Break Ellipta 100/25</td>
<td>Break Ellipta 100/25</td>
<td>Break Ellipta 100/25</td>
</tr>
<tr>
<td>10156M</td>
<td>indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules</td>
<td>1 5 ..</td>
<td>96.38</td>
<td>37.70</td>
<td>Ultibro Breezhaler 110/50</td>
<td>Ultibro Breezhaler 110/50</td>
<td>Ultibro Breezhaler 110/50</td>
</tr>
</tbody>
</table>

**FLUTICASONE + VILAN TEROL**

**Restricted benefit**

Asthma

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

Patient must be aged 12 years or over.

**Note**

This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Note**

This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**INDACATEROL + GLYCOPPYRRONIUM**

**Authority required (STREAMLINED)**

4655 Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**Note**

The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note**

A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note**

A LABA includes indacaterol, salmeterol, eformoterol or vilanterol.

**Note**

This product is not PBS-subsidised for the treatment of asthma.

**Note**

This product is not indicated for the initiation of bronchodilator therapy in COPD.
## RESPIRATORY SYSTEM

### Authority required (STREAMLINED)

#### 4655
Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**Note**

The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note**

A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note**

A LABA includes indacaterol, salmeterol, eformoterol or vilanterol.

**Note**

This product is not PBS-subsidised for the treatment of asthma.

**Note**

This product is not indicated for the initiation of bronchodilator therapy in COPD.

#### 10188F

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### OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

#### Glucocorticoids

### BECLOMETHASONE

**Restricted benefit**

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

#### 8409N

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#### 8408M

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<td>beclomethasone dipropionate inhalation: pressurised, 200</td>
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<td>29.36</td>
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<td>8406K</td>
<td>beclomethasone dipropionate 50 microgram/actuation inhalation: pressurised, 200</td>
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### Budesonide

**Authority required (STREAMLINED)**

Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy.

#### 2066R

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#### 2065Q

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<td>budesonide 500 microgram/2 mL Inhalation: solution, 30 x 2 mL ampoules</td>
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<td>38.20</td>
<td>37.70</td>
<td>Pulmicort Respules</td>
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#### 2070Y

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## RESPIRATORY SYSTEM

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<tr>
<td>NP</td>
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<td>...</td>
<td>31.42</td>
<td>32.57</td>
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<td>18.58</td>
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<td>31.00</td>
<td>32.15</td>
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<td>8148W</td>
<td>fluticasone propionate 250 microgram/actuation inhalation: powder for, 60 actuations</td>
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<td>50.06</td>
<td>37.70</td>
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<td>50.06</td>
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### Anticholinergics

**ACLDININIUM**

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

<table>
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<tr>
<th>Code</th>
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<td>5</td>
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<td>62.73</td>
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**GLYCOPYRRONIUM**

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

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<td>NP</td>
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<td>...</td>
<td>62.73</td>
<td>37.70</td>
<td>seebri breezhaler NV</td>
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**IPRATROPIUM**

**Restricted benefit**

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

**Restricted benefit**

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>8671J</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
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<td>*28.28</td>
<td>29.43</td>
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### RESPIRATORY SYSTEM

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<td>20.68</td>
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<td>3408J</td>
<td>adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe</td>
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<td>106.34</td>
<td>37.70</td>
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<td>8697R</td>
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<td>..</td>
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<td>106.34</td>
<td>37.70</td>
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<tr>
<td>3409K</td>
<td>adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe</td>
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<td>..</td>
<td>..</td>
<td>106.34</td>
<td>37.70</td>
<td>Anapen LM AL</td>
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<td>..</td>
<td>106.34</td>
<td>37.70</td>
<td>EpiPen AL</td>
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### RESPIRATORY SYSTEM

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<td>injection, 1 x 0.3 mL syringe</td>
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</table>

### Selective beta-2-adrenoreceptor agonists

**SALBUTAMOL**
- **1103C NP** salbutamol 2 mg/5 mL oral liquid, 150 mL
  - 2 5 .. *22.54 23.69 Ventolin GK

**TERBUTALINE**
- **1034K NP** terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules
  - 1 .. .. 30.93 32.08 Bricanyl AP

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

#### Xanthines

**THEOPHYLLINE**

**Caution**
Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

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

- **2614N NP** theophylline 133.3 mg/25 mL oral liquid, 500 mL
  - 4 1 5 .. 12.65 13.80 Nuelin IA
- **8230E NP** theophylline 200 mg tablet: modified release, 100 tablets
  - 5 1 5 .. 12.50 13.65 Nuelin-SR 200 IA
- **2634P NP** theophylline 250 mg tablet: modified release, 100 tablets
  - 5 1 5 .. 13.66 14.81 Nuelin-SR 250 IA
- **8231F NP** theophylline 300 mg tablet: modified release, 100 tablets
  - 1 5 5 .. 15.04 16.19 Nuelin-SR 300 IA

#### Leukotriene receptor antagonists

**MONTELUKAST**

**Authority required (STREAMLINED)**
2617
First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

**Note**
Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.
Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

- **8627C NP** montelukast 4 mg tablet: chewable, 28
  - 4 1 5 .. 32.03 33.18 a a Apo-Montelukast TX
  - a Auro-Montelukast Tabs 4 DO
  - a Chem mart Montelukast CH
  - a Lukair FR
  - a Montair 4 GN
  - a Montelukast AN EA
  - a Montelukast GH GQ
  - a Montelukast RBX RA
  - a Montelukast Sandoz 4 SZ
  - a Pharmacor CR
  - a Montelukast 4 Respikast 4 QA
  - a Singulair MK
  - a Terry White Chemists Montelukast TW
  - a T Lukast AF

**MONTELUKAST**

**Authority required (STREAMLINED)**
### RESPIRATORY SYSTEM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2618</td>
<td>First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium <strong>Authority required (STREAMLINED)</strong></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>30.51</td>
<td>31.66</td>
<td>a APO-Montelukast TX a Auro-Montelukast Tabs DO a Chem mart Montelukast CH a Lukair FR a Montair 5 GN a Montelukast AN EA a Montelukast GH GQ a Montelukast RBX RA a Montelukast Sandoz 5 NZ a Pharmacor CR a Montelukast 5 QA a Resipak 5 MK a Tery White Chemists T Lukast TW a T Lukast AF</td>
</tr>
<tr>
<td>3217</td>
<td>Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms <strong>Note</strong> Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma. <strong>Note</strong> No applications for increased maximum quantities and/or repeats will be authorised.</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>8628D np montelukast 5 mg tablet: chewable, 28</td>
</tr>
<tr>
<td>8628D</td>
<td>np montelukast 5 mg tablet: chewable, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>30.51</td>
<td>31.66</td>
<td>a APO-Montelukast TX a Auro-Montelukast Tabs DO a Chem mart Montelukast CH a Lukair FR a Montair 5 GN a Montelukast AN EA a Montelukast GH GQ a Montelukast RBX RA a Montelukast Sandoz 5 NZ a Pharmacor CR a Montelukast 5 QA a Resipak 5 MK a Tery White Chemists T Lukast TW a T Lukast AF</td>
</tr>
</tbody>
</table>

### COUGH AND COLD PREPARATIONS

#### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

**Opium alkaloids and derivatives**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1214X</td>
<td>codeine phosphate 30 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.21</td>
<td>18.36</td>
<td>Fawns and McAllan Proprietary Limited FM</td>
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### ANTIHISTAMINES FOR SYSTEMIC USE

#### ANTIHISTAMINES FOR SYSTEMIC USE

**Phenothiazine derivatives**

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<tr>
<td>194BM</td>
<td>promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.58</td>
<td>31.73</td>
<td>Hospira Pty Limited HH</td>
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## SENSORY ORGANS

### OPHTHALMOLOGICALS

#### ANTINFECTIVES

##### Antibiotics

**AZITHROMYCIN**

**Restricted benefit**

Trachoma

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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<thead>
<tr>
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<tbody>
<tr>
<td>8201P</td>
<td>azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>#23.70</td>
<td>25.20</td>
<td>Zithromax PF</td>
</tr>
<tr>
<td>8336R</td>
<td>azithromycin 500 mg tablet, 2</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.25</td>
<td>14.40</td>
<td>a APO-Azithromycin TX</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>a Azithromycin-GA UA</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Azithromycin Sandoz SZ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Chem mart Azithromycin CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Terry White Chemists Azithromycin TW</td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>a Zithromax PF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Ziticin GN</td>
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**CHLORAMPHENICOL**

<table>
<thead>
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<tr>
<td>2360F</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chlorsig QA</td>
</tr>
<tr>
<td>5055C</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chlorsig QA</td>
</tr>
<tr>
<td>5512D</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chlorsig QA</td>
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<tr>
<td>1171P</td>
<td>chloramphenicol 1% eye ointment, 4 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>10.10</td>
<td>11.25</td>
<td>Chloromycetin PF</td>
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<tr>
<td>5511C</td>
<td>chloramphenicol 1% eye ointment, 4 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>10.10</td>
<td>11.25</td>
<td>Chlorsig QA</td>
</tr>
</tbody>
</table>

**GENTAMICIN**

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected pseudomonal eye infection

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>1441W</td>
<td>gentamicin 0.3% eye drops, 5 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.63</td>
<td>19.78</td>
<td>Genoptic AG</td>
</tr>
</tbody>
</table>

**GENTAMICIN**

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected pseudomonal eye infection

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5566Y</td>
<td>gentamicin 0.3% eye drops, 5 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.63</td>
<td>19.78</td>
<td>Genoptic AG</td>
</tr>
</tbody>
</table>

**TOBRAMYCIN**

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2328M</td>
<td>Suspected pseudomonal eye infection tobramycin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>19.62</td>
<td>20.77</td>
<td>Tobrex AQ</td>
</tr>
<tr>
<td>2329N</td>
<td>tobramycin 0.3% eye ointment, 3.5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>22.72</td>
<td>23.87</td>
<td>Tobrex AQ</td>
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<tr>
<td>5569D</td>
<td>tobramycin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>19.62</td>
<td>20.77</td>
<td>Tobrex AQ</td>
</tr>
<tr>
<td>5570E</td>
<td>tobramycin 0.3% eye ointment, 3.5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>22.72</td>
<td>23.87</td>
<td>Tobrex AQ</td>
</tr>
</tbody>
</table>

**Antivirals**

**ACICLOVIR**

Restricted benefit
Herpes simplex keratitis

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

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1002R</td>
<td>aciclovir 3% eye ointment, 4.5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>37.80</td>
<td>37.70</td>
<td>Zovirax GK</td>
</tr>
<tr>
<td>5501M</td>
<td>aciclovir 3% eye ointment, 4.5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>37.80</td>
<td>37.70</td>
<td>Zovirax GK</td>
</tr>
</tbody>
</table>

**Fluoroquinolones**

**CIPROFLOXACIN**

Authority required
Bacterial keratitis

Treatment criteria:
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1217C</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*28.82</td>
<td>29.97 a</td>
<td>CiloQuin IQ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*2.06</td>
<td>*30.88</td>
<td>29.97 a</td>
</tr>
</tbody>
</table>

**CIPROFLOXACIN**

Authority required
Bacterial keratitis

Treatment criteria:
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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<td>5564W</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
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<td>..</td>
<td>..</td>
<td>*28.82</td>
<td>29.97 a</td>
<td>CiloQuin IQ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*2.06</td>
<td>*30.88</td>
<td>29.97 a</td>
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</tbody>
</table>

**OFLOXACIN**

Authority required
Bacterial keratitis

Treatment criteria:
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>5567B</td>
<td>ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*35.64</td>
<td>36.79</td>
<td>Ocuflox AG</td>
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**OFLOXACIN**

Authority required
# SENSORY ORGANS

<table>
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<tr>
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<tr>
<td>8383F</td>
<td>ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>* 35.64</td>
<td>36.79</td>
<td>Ocufox AG</td>
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**ANTIIINFLAMMATORY AGENTS**

**Corticosteroids, plain**

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<tbody>
<tr>
<td>1288T</td>
<td>DEXAMETHASONE Eye drops 1 mg per ml (0.1%), 5 mL, 1</td>
<td>⁄1</td>
<td>2</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Maxidex AQ</td>
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**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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<tr>
<td>5565X</td>
<td>DEXAMETHASONE Eye drops 1 mg per ml (0.1%), 5 mL, 1</td>
<td>⁄1</td>
<td>..</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Maxidex AQ</td>
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**Note**

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<tr>
<td>1204J</td>
<td>fluorometholone 0.1% eye drops, 5 mL</td>
<td>⁄1</td>
<td>5</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Flucon AQ</td>
</tr>
</tbody>
</table>

**Note**

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<tr>
<td>5513E</td>
<td>fluorometholone 0.1% eye drops, 5 mL</td>
<td>⁄1</td>
<td>..</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Flucon AQ</td>
</tr>
</tbody>
</table>

**Note**

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<tr>
<td>1438Q</td>
<td>fluorometholone acetate 0.1% eye drops, 5 mL</td>
<td>⁄1</td>
<td>2</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Flarex AQ</td>
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</table>

**Note**

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<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5533F</td>
<td>fluorometholone acetate 0.1% eye drops, 5 mL</td>
<td>⁄1</td>
<td>..</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Flarex AQ</td>
</tr>
</tbody>
</table>

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2441L</td>
<td>hydrocortisone acetate 1% eye ointment, 5 g</td>
<td>⁄1</td>
<td>..</td>
<td>..</td>
<td>13.03</td>
<td>14.18</td>
<td>Hycor QA</td>
</tr>
</tbody>
</table>

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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<tbody>
<tr>
<td>5516H</td>
<td>hydrocortisone acetate 1% eye ointment, 5 g</td>
<td>⁄1</td>
<td>..</td>
<td>..</td>
<td>13.03</td>
<td>14.18</td>
<td>Hycor QA</td>
</tr>
</tbody>
</table>

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Corticosteroids and mydriatics in combination**

**PHENYLEPHRINE + PREDNISOLONE ACETATE**

**Restricted benefit**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3112T</td>
<td>phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL</td>
<td>⁄1</td>
<td>2</td>
<td>..</td>
<td>26.16</td>
<td>27.31</td>
<td>Prednefrin Forte AG</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Premium $</td>
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<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
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<td>------------</td>
<td>-----------</td>
<td>-------------------------------</td>
<td>-------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>5568C</td>
<td>phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL</td>
<td>‡1 .. ..</td>
<td>26.16</td>
<td>27.31</td>
<td>Prednefrin Forte</td>
<td>AG</td>
<td></td>
</tr>
</tbody>
</table>

**Antiinflammatory agents, non-steroids**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5514F</td>
<td>flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules</td>
<td>1 .. ..</td>
<td>17.16</td>
<td>18.31</td>
<td>Ocufen</td>
<td>AG</td>
<td></td>
</tr>
<tr>
<td>8699W</td>
<td>flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules</td>
<td>1 .. ..</td>
<td>17.16</td>
<td>18.31</td>
<td>Ocufen</td>
<td>AG</td>
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</tr>
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</table>

**ANTIGLAUCOMA PREPARATIONS AND MIOTICS**

**Sympathomimetics in glaucoma therapy**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>8083K</td>
<td>apraclonidine 0.5% eye drops, 10 mL</td>
<td>‡1 2 ..</td>
<td>42.11</td>
<td>37.70</td>
<td>Iopidine 0.5%</td>
<td>AQ</td>
<td></td>
</tr>
</tbody>
</table>

**BRIMONIDINE**

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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</tr>
</thead>
<tbody>
<tr>
<td>5563T</td>
<td>brimonidine tartrate 0.15% eye drops, 5 mL</td>
<td>‡1 5 ..</td>
<td>20.48</td>
<td>21.63</td>
<td>Alphagan P 1.5</td>
<td>AG</td>
<td></td>
</tr>
<tr>
<td>5534G</td>
<td>brimonidine tartrate 0.2% eye drops, 5 mL</td>
<td>‡1 5 ..</td>
<td>20.48</td>
<td>21.63</td>
<td>Enidin</td>
<td>PE</td>
<td></td>
</tr>
</tbody>
</table>

**BRIMONIDINE + TIMOLOL**

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<tbody>
<tr>
<td>5535H</td>
<td>brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL</td>
<td>‡1 5 ..</td>
<td>26.37</td>
<td>27.52</td>
<td>Combigan</td>
<td>AG</td>
<td></td>
</tr>
</tbody>
</table>

**BRIMONIDINE + TIMOLOL**

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<tbody>
<tr>
<td>5536H</td>
<td>brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL</td>
<td>‡1 5 ..</td>
<td>26.37</td>
<td>27.52</td>
<td>Combigan</td>
<td>AG</td>
<td></td>
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<tr>
<td>Code</td>
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<td>-----------</td>
<td>---------------------------------</td>
<td>-------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>8826M</td>
<td>Patient must have open-angle glaucoma; OR Patient must have ocular hypertension. brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL</td>
<td>‡1 5 ...</td>
<td>26.37</td>
<td>27.52</td>
<td>Combigan AG</td>
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**Parasympathomimetics**

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2595N</td>
<td>pilocarpine hydrochloride 1% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>12.87</td>
<td>14.02</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2596P</td>
<td>pilocarpine hydrochloride 2% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>14.12</td>
<td>15.27</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2598R</td>
<td>pilocarpine hydrochloride 4% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>16.97</td>
<td>18.12</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note**

**PILOCARPINE**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>5536J</td>
<td>pilocarpine hydrochloride 1% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>12.87</td>
<td>14.02</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5537K</td>
<td>pilocarpine hydrochloride 2% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>14.12</td>
<td>15.27</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5538L</td>
<td>pilocarpine hydrochloride 4% eye drops, 15 mL</td>
<td>‡1 5 ...</td>
<td>16.97</td>
<td>18.12</td>
<td>Isopto Carpine AQ</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Carbonic anhydrase inhibitors**

**ACETAZOLAMIDE**

**Note**

**Continuing Therapy Only:**

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

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1004W</td>
<td>acetzolamide 250 mg tablet, 100</td>
<td>1 3 ...</td>
<td>24.13</td>
<td>25.28</td>
<td>Diamox QA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE**

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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</thead>
<tbody>
<tr>
<td>5540N</td>
<td>brinzolamide 1% eye drops, 5 mL</td>
<td>‡1 5 ...</td>
<td>23.11</td>
<td>24.26</td>
<td>* BrinzQuin IQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8483L</td>
<td>brinzolamide 1% eye drops, 5 mL</td>
<td>‡1 5 ...</td>
<td>23.11</td>
<td>24.26</td>
<td>* BrinzQuin IQ</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + TIMOLOL**

**Restricted benefit**

**Elevated intra-ocular pressure**

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

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</thead>
<tbody>
<tr>
<td>3438Y</td>
<td>brinzolamide 1% + timolol 0.5% eye drops, 5 mL</td>
<td>‡1 5 ...</td>
<td>27.22</td>
<td>28.37</td>
<td>Azarga AQ</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + TIMOLOL**

**Restricted benefit**
SENSORY ORGANS

Elevated intra-ocular pressure

Clinical criteria:
The condition must have been inadequately controlled with monotherapy,
AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

Note
Shared Care Model:
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5562R OP
brinzolamide 1% + timolol 0.5% eye drops, 5 mL
‡1 5 .. 27.22 28.37 Azarga AQ

DORZOLAMIDE

Note
Shared Care Model:
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5541P OP
dorzolamide 2% (20 mg/mL) eye drops, 5 mL
‡1 5 .. 19.26 20.41 a Trusamide QA
a Trusopt MK

8488R

dorzolamide 2% (20 mg/mL) eye drops, 5 mL
‡1 5 .. 19.26 20.41 a Trusamide QA
a Trusopt MK

DORZOLAMIDE + TIMOLOL

Restricted benefit
Elevated intra-ocular pressure

Clinical criteria:
The condition must have been inadequately controlled with monotherapy,
AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

Note
Shared Care Model:
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5542Q OP
dorzolamide 2% + timolol 0.5% eye drops, 5 mL
‡1 5 .. 24.19 25.34 a Cosdor QA
a Cosopt MK
a Dorzolamide/Timolol Sandoz 20/5 SZ

DORZOLAMIDE + TIMOLOL

Restricted benefit
Elevated intra-ocular pressure

Clinical criteria:
The condition must have been inadequately controlled with monotherapy,
AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

8567X
dorzolamide 2% + timolol 0.5% eye drops, 5 mL
‡1 5 .. 24.19 25.34 a Cosdor QA
a Cosopt MK
a Dorzolamide/Timolol Sandoz 20/5 SZ

Beta blocking agents
<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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</thead>
<tbody>
<tr>
<td><strong>BETAXOLOL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2811Y</td>
<td>betaxolol 0.25% eye drops, 5 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>15.11</td>
<td>16.26</td>
<td>Betoptic S AQ</td>
</tr>
<tr>
<td>2825Q</td>
<td>betaxolol 0.5% eye drops, 5 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>15.11</td>
<td>16.26 a</td>
<td>BetoQuin IQ</td>
</tr>
<tr>
<td><strong>TIMOLOL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5543R OP</td>
<td>betaxolol 0.25% eye drops, 5 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>15.11</td>
<td>16.26</td>
<td>Betoptic S AQ</td>
</tr>
<tr>
<td>5544T OP</td>
<td>betaxolol 0.5% eye drops, 5 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>15.11</td>
<td>16.26 a</td>
<td>BetoQuin IQ</td>
</tr>
<tr>
<td><strong>Prostaglandin analogues</strong></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td><strong>BIMATOPROST</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5551E OP</td>
<td>bimatoprost 0.03% eye drops, 3 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>42.48</td>
<td>37.70</td>
<td>Lumigan AG</td>
</tr>
<tr>
<td>10053D OP</td>
<td>bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses ‡1</td>
<td>5</td>
<td>..</td>
<td>36.91</td>
<td>37.70</td>
<td>Lumigan PF AG</td>
</tr>
<tr>
<td><strong>BIMATOPROST + TIMOLOL</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>8620Q</td>
<td>bimatoprost 0.03% eye drops, 3 mL ‡1</td>
<td>5</td>
<td>..</td>
<td>42.48</td>
<td>37.70</td>
<td>Lumigan AG</td>
</tr>
<tr>
<td>10046R</td>
<td>bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses ‡1</td>
<td>5</td>
<td>..</td>
<td>36.91</td>
<td>37.70</td>
<td>Lumigan PF AG</td>
</tr>
</tbody>
</table>
# SENSORY ORGANS

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>5558M</td>
<td>Bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL</td>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>46.94</td>
<td>37.70</td>
<td>Ganfort 0.3/5 AG</td>
</tr>
<tr>
<td>10108B</td>
<td>Bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses</td>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>41.21</td>
<td>37.70</td>
<td>GANfort PF 0.3/5 AG</td>
</tr>
</tbody>
</table>

**BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

<table>
<thead>
<tr>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>9464D</td>
<td>Bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL</td>
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<td>Ganfort 0.3/5 AG</td>
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**BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

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<tr>
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**LATANOPROST**

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<td>25.21</td>
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<td>25.21</td>
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</table>

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.
### Latanoprost + Timolol

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, **AND**

- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<td>latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL</td>
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<td>37.70</td>
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### Tafluprost

**Note**

Shared Care Model:

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<td>2748P</td>
<td>tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses</td>
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### Timolol + Travoprost

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
SENSORY ORGANS

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<tr>
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<td></td>
<td>Patient must have open-angle glaucoma; OR</td>
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</table>

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.
**SENSORY ORGANS**

**Subfoveal choroidal neovascularisation (CNV)**

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD),

- The condition must be diagnosed by fluorescein angiography,

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

- Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone.

- A written application must include:
  a) a completed authority prescription form;
  b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
  c) a copy of the fluorescein angiogram.

- A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

**Note**

- The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**

- Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

**Note**

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

- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

- Applications for authority to prescribe should be forwarded to:

  Department of Human Services
  Prior Written Approval of Complex Drugs
  Reply Paid 9826
  GPO Box 9826
  HOBART TAS 7001

**Note**

- Special Pricing Arrangements apply.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD),

- The treatment must be the sole PBS-subsidised therapy for this condition,

- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist.

**Note**

- Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.
SENSORY ORGANS

Note
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Note
Special Pricing Arrangements apply.

<table>
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<tr>
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<td>aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial</td>
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<td>2</td>
<td>..</td>
<td>1431.50</td>
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</table>

RANIBIZUMAB

Authority required
Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:
The condition must be due to age-related macular degeneration (AMD),

AND
The condition must be diagnosed by fluorescein angiography,

AND
The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.

A written application must include:
a) a completed authority prescription form;
b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
c) a copy of the fluorescein angiogram.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Note
Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required
### SUBFOVEAL CHOROIDAL NEOVASCULARISATION (CNV)

**Treatment Phase:** Continuing treatment

#### Clinical criteria:
- The condition must be due to age-related macular degeneration (AMD),
- The treatment must be the sole PBS-subsidised therapy for this condition,
- Patient must have previously been granted an authority prescription for the same eye.

#### Treatment criteria:
- Must be treated by an ophthalmologist.

**Note**
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Special Pricing Arrangements apply.

**Note**
Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

#### 10138N
- **Code:** 10138N
- **Name:** ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe
- **Max. Qty (Packs):** 1
- **No. of Rpts:** 2
- **Dispensed Price for Max. Qty:** $1431.50
- **Premium:** $37.70
- **Brand Name and Manufacturer:** Lucentis

#### 1382R
- **Code:** 1382R
- **Name:** ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial
- **Max. Qty (Packs):** 1
- **No. of Rpts:** 2
- **Dispensed Price for Max. Qty:** $1431.50
- **Premium:** $37.70
- **Brand Name and Manufacturer:** Lucentis

### VERTEPORFIN

#### Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
- (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:
- Medicare Australia
- Prior Written Approval of Specialised Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum Authority required

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes
the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin.

Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

**Authority required**

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin.

Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

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**OTHER OPHTHALMOLOGICALS**

*Other ophthalmologicals*

**CARBOMER + TRIGLYCERIDE LIPIDS**

*Authority required (STREAMLINED)*

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**CARBOMER + TRIGLYCERIDE LIPIDS**

*Authority required*

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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**CARBOMER-974**

*Authority required*

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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**CARBOMER-974**

*Authority required (STREAMLINED)*

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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**CARBOMER-980**

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# SENSORY ORGANS

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## CARMELLOSE SODIUM

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **5505R OP**
  - carmelllose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses
  - 3 5 ... *40.76 32.78 Optifresh Plus PP

- **5509Y OP**
  - carmelllose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses
  - 4 5 ... *40.76 32.78 TheraTears CX

- **5506T OP**
  - carmelllose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses
  - 3 5 ... *31.63 32.78 Optifresh Tears PP

- **5510B OP**
  - carmelllose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses
  - 3 5 ... *34.42 35.57 TheraTears CX

## CARMELLOSE SODIUM + GLYCEROL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**Note**

The in-use shelf life of Optive is 6 months from the date of opening.

- **5556K OP**
  - carmelllose sodium 0.5% + glycerol 0.9% eye drops, 15 mL
  - ‡1 3 ... 10.93 12.08 Optive AG

- **9355J NP**
  - carmelllose sodium 0.5% + glycerol 0.9% eye drops, 15 mL
  - ‡1 3 ... 10.93 12.08 Optive AG

## CARMELLOSE SODIUM + GLYCEROL

**Restricted benefit**

For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

The in-use shelf life of Optive is 6 months from the date of opening.

- **9356K**
  - carmelllose sodium 0.5% + glycerol 0.9% eye drops, 15 mL
  - ‡1 7 ... 10.93 12.08 Optive AG

## CARMELLOSE SODIUM + GLYCEROL

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **5561Q OP**
  - carmelllose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses
  - 3 5 ... *36.40 37.55 Optive AG

## CARMELLOSE SODIUM + GLYCEROL

**Authority required (STREAMLINED)**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **13598**
  - carmelllose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses
  - 3 5 ... *36.40 37.55 Optive AG

## DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

- **1509K NP**
  - dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL
  - ‡1 5 ... 10.83 11.98 Poly-Tears IQ

- **5520M OP**
  - dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL
  - ‡1 5 ... 10.83 11.98 Poly-Tears IQ

- **1509K NP**
  - dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL
  - ‡2 0.4 12.87 11.98 Tears Naturale AQ

- **5520M OP**
  - dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL
  - ‡2 0.4 12.87 11.98 Tears Naturale AQ
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<td>5</td>
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<td>*35.41</td>
<td>36.56</td>
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<td>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops</td>
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<td>‡1</td>
<td>5</td>
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<td>11.76</td>
<td>a In a Wink Moisturising IQ</td>
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<td>10.61</td>
<td>11.76</td>
<td>a In a Wink Moisturising IQ</td>
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<td>2956N</td>
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<td>11.76</td>
<td>a Methopt QA</td>
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<td>11.76</td>
<td>a Methopt QA</td>
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<tr>
<td>9213X</td>
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<td>10.61</td>
<td>11.76</td>
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<td>11.76</td>
<td>a Methopt QA</td>
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<tr>
<td>5519L</td>
<td>hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g</td>
<td>‡1</td>
<td>5</td>
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<td>11.76</td>
<td>a HPMC PAA IQ</td>
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<td>1.95</td>
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<td>11.76</td>
<td>a HPMC PAA IQ</td>
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<tr>
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<td>11.76</td>
<td>a HPMC PAA</td>
<td>IQ</td>
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<tr>
<td>1750D</td>
<td>paraffin 1/g eye ointment, 2 x 3.5 g tubes</td>
<td>‡1 5</td>
<td>..</td>
<td>20.94</td>
<td>22.09</td>
<td>a Ircal</td>
<td>PE</td>
</tr>
<tr>
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<td>5522P</td>
<td>paraffin 1/g eye ointment, 2 x 3.5 g tubes</td>
<td>‡1 5</td>
<td>..</td>
<td>20.94</td>
<td>22.09</td>
<td>a Refresh Night Time Poly Visc</td>
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<tr>
<td>1754H</td>
<td>paraffin 1/g eye ointment, 3.5 g</td>
<td>2 5</td>
<td>..</td>
<td>*21.58</td>
<td>22.73</td>
<td>a Poly Visc</td>
<td>AQ</td>
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<tr>
<td>NP</td>
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<tr>
<td>5523Q</td>
<td>paraffin 1/g eye ointment, 3.5 g</td>
<td>2 5</td>
<td>..</td>
<td>*21.58</td>
<td>22.73</td>
<td>a Poly Visc</td>
<td>AQ</td>
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<tr>
<td>OP</td>
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<tr>
<td>2167C</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g</td>
<td>2 5</td>
<td>..</td>
<td>*21.58</td>
<td>22.73</td>
<td>VitA-POS</td>
<td>AE</td>
</tr>
<tr>
<td>OP</td>
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</tr>
<tr>
<td>2222Y</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g</td>
<td>2 5</td>
<td>..</td>
<td>*21.58</td>
<td>22.73</td>
<td>VitA-POS</td>
<td>AE</td>
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<td>NP</td>
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<tr>
<td>2202X</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g</td>
<td>2 11</td>
<td>..</td>
<td>*21.58</td>
<td>22.73</td>
<td>VitA-POS</td>
<td>AE</td>
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**Note**
No increase in the maximum number of repeats may be authorised.

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Restricted benefit**
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5524R</td>
<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</td>
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<td>10.93</td>
<td>12.08</td>
<td>Systane AQ</td>
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<tr>
<td>8676P</td>
<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</td>
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<td>10.93</td>
<td>12.08</td>
<td>Systane AQ</td>
<td></td>
<td></td>
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</tbody>
</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Restricted benefit**

For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
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<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</td>
<td>‡1 11 ..</td>
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<td>12.08</td>
<td>Systane AQ</td>
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**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5532E</td>
<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses</td>
<td>2 5 ..</td>
<td>*34.42</td>
<td>35.57</td>
<td>Systane AQ</td>
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**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

**Authority required (STREAMLINED)**

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<tr>
<td>9170P</td>
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<td>35.57</td>
<td>Systane AQ</td>
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**POLYVINYL ALCOHOL**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2682E</td>
<td>polyvinyl alcohol 1.4% eye drops, 15 mL</td>
<td>‡1 5 ..</td>
<td>10.61</td>
<td>11.76</td>
<td>a PVA Tears PE</td>
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<td>11.76</td>
<td>a PVA Tears PE</td>
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<tr>
<td>5527X</td>
<td>polyvinyl alcohol 1.4% eye drops, 15 mL</td>
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<td>a Vistil AE</td>
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<td>5528Y</td>
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<td>11.76</td>
<td>a Vistil Forte AE</td>
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<tr>
<td>8832W</td>
<td>polyvinyl alcohol 3% eye drops, 15 mL</td>
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<td>11.76</td>
<td>11.76</td>
<td>a Vistil Forte AE</td>
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**POLYVINYL ALCOHOL**

**Restricted benefit**

For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

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<td>a PVA Tears PE</td>
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<tr>
<td>9221H</td>
<td>polyvinyl alcohol 1.4% eye drops, 15 mL</td>
<td>‡1 11 ..</td>
<td>12.21</td>
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<td>a Liquifilm Tears AG</td>
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<td>9223K</td>
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### SENSORY ORGANS

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<td>4105</td>
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<tr>
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<td>Severe dry eye syndrome</td>
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<td></td>
<td>Patient must be sensitive to preservatives in multi-dose eye drops.</td>
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<tr>
<td></td>
<td>The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.</td>
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<td>2181T</td>
<td>sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL</td>
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<td>33.96</td>
<td>35.11</td>
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<td>AE</td>
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<tr>
<td>2253N</td>
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<td>33.96</td>
<td>35.11</td>
<td>Hylo-Forte</td>
<td>AE</td>
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### SOY LECITHIN + TOCOPHEROLS + VITAMIN A

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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5545W</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>2 5</td>
<td>..</td>
<td>*36.40</td>
<td>37.55</td>
<td>tearsagain</td>
<td>RB</td>
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### SOY LECITHIN + TOCOPHEROLS + VITAMIN A

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<thead>
<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>944BG</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>2 5</td>
<td>..</td>
<td>*36.40</td>
<td>37.55</td>
<td>tearsagain</td>
<td>RB</td>
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### OTOLOGICALS

#### ANTIINFECTIVES

**Antiinfectives**

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<tbody>
<tr>
<td>1172Q</td>
<td>chloramphenicol 0.5% ear drops, 5 mL</td>
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<td>11.39</td>
<td>12.54</td>
<td>Chloromycetin</td>
<td>PF</td>
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</table>

### CIPROFLOXACIN

**Authority required**

- Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older
- Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane
- Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispersed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2480M</td>
<td>ciprofloxacin 0.3% ear drops, 5 mL</td>
<td>‡1 1</td>
<td>..</td>
<td>19.62</td>
<td>20.77</td>
<td>Ciloxan</td>
<td>AQ</td>
</tr>
</tbody>
</table>
### CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

*Corticosteroids and antiinfectives in combination*

#### DEXAMETHASONE + FRAMYCETIN SULFATE + GRAMICIDIN

<table>
<thead>
<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2781J</td>
<td>dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>10.28</td>
<td>11.43</td>
<td>a Otodex AV</td>
</tr>
<tr>
<td>2974M</td>
<td>triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>8.52</td>
<td>9.67</td>
<td>a Otocomb Otic FM</td>
</tr>
<tr>
<td>2971J</td>
<td>triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.43</td>
<td>12.58</td>
<td>a Kenacomb Otic QA</td>
</tr>
</tbody>
</table>

#### TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2974M</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.08</td>
<td>12.23</td>
<td>a Soframycin SW</td>
</tr>
<tr>
<td>2971J</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.08</td>
<td>12.23</td>
<td>a Soframycin SW</td>
</tr>
</tbody>
</table>

### OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

#### ANTIINFECTIVES

*Antiinfectives*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1440T</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.08</td>
<td>12.23</td>
<td>Soframycin SW</td>
</tr>
<tr>
<td>5557L</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.08</td>
<td>12.23</td>
<td>Soframycin SW</td>
</tr>
</tbody>
</table>
# VARIOUS

## ALLERGENS

**Allergen extracts**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2886X</td>
<td>Bee venom 550 microgram injection [1 x 550 microgram vial] (&amp;) inert substance diluent [4 vials], 1 pack</td>
<td>1</td>
<td>..</td>
<td>238.72</td>
<td>37.70</td>
<td>Albey Bee Venom HL</td>
</tr>
<tr>
<td>2918N</td>
<td>Paper wasp venom is not European wasp venom.</td>
<td>1</td>
<td>..</td>
<td>238.72</td>
<td>37.70</td>
<td>Albey Paper Wasp Venom HL</td>
</tr>
<tr>
<td>2883R</td>
<td>Vespula spp venom 550 microgram injection [1 x 550 microgram vial] (&amp;) inert substance diluent [4 vials], 1 pack</td>
<td>1</td>
<td>..</td>
<td>238.72</td>
<td>37.70</td>
<td>Albey Yellow Jacket Venom HL</td>
</tr>
</tbody>
</table>

### VESPULA SPP VENOM

Note

Note: Paper wasp venom is not European wasp venom.

## ALL OTHER THERAPEUTIC PRODUCTS

### Antidotes

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2192J</td>
<td>Naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
<td>5</td>
<td>..</td>
<td>*105.16</td>
<td>37.70</td>
<td>Naloxone minijet UC</td>
</tr>
<tr>
<td>2196N</td>
<td>Naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
<td>5</td>
<td>..</td>
<td>*105.16</td>
<td>37.70</td>
<td>Naloxone minijet UC</td>
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</table>

### Drugs for treatment of hyperkalemia and hyperphosphatemia

**LANTHANUM**

**Authority required (STREAMLINED)**

**4827**

Hyperphosphataemia

**Treatment Phase:** Maintenance following initiation and stabilisation

**Clinical criteria:**

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

**Note**

**Shared Care Model:**

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9405B</td>
<td>Lanthanum Tablet, chewable, 1000 mg (as carbonate hydrate), 90</td>
<td>1</td>
<td>5</td>
<td>504.37</td>
<td>37.70</td>
<td>Fosrenol ZI</td>
</tr>
<tr>
<td>9403X</td>
<td>Lanthanum Tablet, chewable, 500 mg (as carbonate hydrate), 90</td>
<td>1</td>
<td>5</td>
<td>306.22</td>
<td>37.70</td>
<td>Fosrenol ZI</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Dispensed Price for Max. Qty $</td>
<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------</td>
<td>-----------------</td>
<td>------------</td>
<td>--------------------------------</td>
<td>------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>9404Y</td>
<td>LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>449.77</td>
<td>37.70</td>
</tr>
<tr>
<td>9404Y</td>
<td>LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90</td>
<td>90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2142R</td>
<td>sevelamer hydrochloride 800 mg tablet, 180 mg tablet: chewable, 90</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>358.07</td>
<td>37.70</td>
</tr>
<tr>
<td>10250L</td>
<td>iron (as sucroferric oxyhydroxide) 900 mg tablet: chewable, 90</td>
<td>1</td>
<td>5</td>
<td></td>
<td>429.82</td>
<td>37.70</td>
</tr>
</tbody>
</table>

**SEVELAMER**

*Authority required (STREAMLINED)*

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

The condition must not be adequately controlled by calcium,

**AND**

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

**AND**

The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

**Note**

Shared Care Model:

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

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2142R</td>
<td>sevelamer hydrochloride 800 mg tablet, 180 mg tablet: chewable, 90</td>
<td>1</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SUCROFERRIC OXYHYDROXIDE**

*Authority required (STREAMLINED)*

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

The condition must not be adequately controlled by calcium,

**AND**

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

**AND**

The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

**Note**

Shared Care Model:

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

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2142R</td>
<td>sevelamer hydrochloride 800 mg tablet, 180 mg tablet: chewable, 90</td>
<td>1</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Detoxifying agents for antineoplastic treatment**

**FOLINIC ACID**

*Note*

For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8812T</td>
<td>folinic acid 100 mg/10 mL injection, 1 x 10 mL vial</td>
<td>10</td>
<td>1</td>
<td>..</td>
<td>*54.76</td>
<td>37.70</td>
<td>Calcium Folate Ebewe</td>
</tr>
<tr>
<td>1704Q</td>
<td>folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>54.81</td>
<td>37.70</td>
<td>Leucovorin Calcium (Pfizer Australia Pty Ltd)</td>
</tr>
<tr>
<td>2308L</td>
<td>folinic acid 15 mg tablet, 10</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>96.65</td>
<td>37.70</td>
<td>Leucovorin Calcium (Hospira Pty Limited)</td>
</tr>
<tr>
<td>8740B</td>
<td>folinic acid 50 mg/5 mL injection, 1 x 5 mL vial</td>
<td>10</td>
<td>2</td>
<td>..</td>
<td>*58.56</td>
<td>37.70</td>
<td>Leucovorin Calcium (Hospira Pty Limited)</td>
</tr>
<tr>
<td>1610R</td>
<td>folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>58.56</td>
<td>37.70</td>
<td>Leucovorin Calcium (Pfizer Australia Pty Ltd)</td>
</tr>
<tr>
<td>8079F</td>
<td>mesna 1 g/10 mL injection, 15 x 10 mL ampoules</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>224.15</td>
<td>37.70</td>
<td>Uromitexan</td>
</tr>
<tr>
<td>8078E</td>
<td>mesna 400 mg/4 mL injection, 15 x 4 mL ampoules</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>103.62</td>
<td>37.70</td>
<td>Uromitexan</td>
</tr>
</tbody>
</table>

**FOLINIC ACID**

**Restricted benefit**
Antidote to folic acid antagonists

**Note**
For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

**MESNA**

**Restricted benefit**
 Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide

**Drugs for treatment of hypercalcemia**

**PHOSPHORUS**

**Authority required (STREAMLINED)**

1099 Familial hypophosphataemia

**Authority required (STREAMLINED)**

1157 Hypercalcaemia

**Authority required (STREAMLINED)**

1167 Hypophosphataemic rickets

**Authority required (STREAMLINED)**

1447 Vitamin D-resistant rickets

**Other therapeutic products**

**POLYLACTIC ACID**

**Authority required**

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**Note**
Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.
Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**Note**
Authority applications to prescribe poly-L-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

- **9476R** poly-L-lactic acid 150 mg injection, 1 x 150 mg vial
  - Max. Qty (Packs): 2
  - No. of Rpts: ..
  - Dispensed Price for Max. Qty: *446.80
  - Premium: 37.70
  - Maximum Recordable Value for Safety Net: 37.70
  - Brand Name and Manufacturer: Sculptra SW

**DIAGNOSTIC AGENTS**

**URINE TESTS**

- **3106L**
  - **NP**
  - glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips
  - Max. Qty (Packs): 2
  - No. of Rpts: 2
  - Dispensed Price for Max. Qty: *17.64
  - Premium: 18.79
  - Maximum Recordable Value for Safety Net: 18.79
  - Brand Name and Manufacturer: Keto-Diabur- Test 5000 RD

- **3107M**
  - **NP**
  - glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips
  - Max. Qty (Packs): 2
  - No. of Rpts: 2
  - Dispensed Price for Max. Qty: *17.76
  - Premium: 18.91
  - Maximum Recordable Value for Safety Net: 18.91
  - Brand Name and Manufacturer: Keto-Diastix BN

**GLUCOSE AND KETONE INDICATOR URINE**

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

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

- **9254C**
  - glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips
  - Max. Qty (Packs): 2
  - No. of Rpts: 4
  - Dispensed Price for Max. Qty: *17.64
  - Premium: 18.79
  - Maximum Recordable Value for Safety Net: 18.79
  - Brand Name and Manufacturer: Keto-Diabur- Test 5000 RD

- **9255D**
  - glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips
  - Max. Qty (Packs): 2
  - No. of Rpts: 4
  - Dispensed Price for Max. Qty: *17.76
  - Premium: 18.91
  - Maximum Recordable Value for Safety Net: 18.91
  - Brand Name and Manufacturer: Keto-Diastix BN

**GLUCOSE INDICATOR URINE**

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

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

- **9253B**
  - glucose indicator urine strip: diagnostic, 50 diagnostic strips
  - Max. Qty (Packs): 2
  - No. of Rpts: 4
  - Dispensed Price for Max. Qty: *20.16
  - Premium: 21.31
  - Maximum Recordable Value for Safety Net: 21.31
  - Brand Name and Manufacturer: Diastix BN

**OTHER DIAGNOSTIC AGENTS**

**Tests for diabetes**

**GLUCOSE INDICATOR BLOOD**

**Restricted benefit**
Blood glucose monitoring.

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

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

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

- **10099M**
  - glucose indicator blood strip: diagnostic, 100
  - Max. Qty (Packs): 1
  - No. of Rpts: 11
  - Dispensed Price for Max. Qty: 53.50
  - Premium: 37.70
  - Maximum Recordable Value for Safety Net: 37.70
  - Brand Name and Manufacturer: GoodLife JN

- **10141R**
  - glucose indicator blood strip: diagnostic, 100
  - Max. Qty (Packs): 1
  - No. of Rpts: 11
  - Dispensed Price for Max. Qty: 53.50
  - Premium: 37.70
  - Maximum Recordable Value for Safety Net: 37.70
  - Brand Name and Manufacturer: EasyMate II WI
<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10164Y</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>Contour next IK</td>
</tr>
<tr>
<td>10222B</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>Dario UH</td>
</tr>
<tr>
<td>1518X</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>Contour IK</td>
</tr>
<tr>
<td>1520B</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>BGStar SW</td>
</tr>
<tr>
<td>2568E</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>TRUEresult NX</td>
</tr>
<tr>
<td>2571H</td>
<td>glucose indicator blood strip: diagnostic, 100</td>
<td>‡1</td>
<td>11</td>
<td>53.50</td>
<td>37.70</td>
<td>TRUEbalance NX</td>
</tr>
<tr>
<td>2602Y</td>
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### GENERAL NUTRIENTS

#### OTHER NUTRIENTS

**TRIGLYCERIDES LONG CHAIN**

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**

Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

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**TRIGLYCERIDES MEDIUM CHAIN**

**Authority required**

- Chylous ascites
- Chylothorax
- Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders
- Hyperlipoproteinaemia type 1
- Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet
- Long chain fatty acid oxidation disorders

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**TRIGLYCERIDES MEDIUM CHAIN**

**Authority required**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.
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**Authority required**
Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
- Patient must have chyloous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

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

**Fat/carbohydrates/proteins/minerals/vitamins, combinations**

**AMINO ACID SYNTHETIC FORMULA**

**Authority required**
Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.
- AND
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Treatment Phase:** Initial treatment for up to 6 months

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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

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

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**AMINO ACID SYNTHETIC FORMULA**

**Authority required**
Cows’ milk anaphylaxis

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk protein enteropathy

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

**AND**
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

**Note**
### AMINO ACID SYNTHETIC FORMULA

**Authority required**

Eosinophilic oesophagitis

**Treatment Phase:** Initial treatment for up to 3 months

**Clinical criteria:**

Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

Patient must be 18 years of age or less.

**Treatment criteria:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

Patient must be 18 years of age or less.

**Treatment criteria:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

### AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority required**

Cows' milk protein enteropathy

**Treatment Phase:** Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
The condition must not be isolated infant colic or reflux.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
The condition must not be isolated infant colic or reflux.

Population criteria:
Patient must be older than 24 months of age.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note
No increase in the maximum quantity or number of units may be authorised.
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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Authority required**

*Cows' milk anaphylaxis*

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

*Cows' milk protein enteropathy*

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

*Severe cows' milk protein enteropathy with failure to thrive*

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

AND
Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Eosinophilic oesophagitis

**Clinical criteria:**
Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
Patient must be 18 years of age or less.

**Treatment criteria:**
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.
Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

Patient must be 18 years of age or less.

**Treatment criteria:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

---

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Clinical criteria:**

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Clinical criteria:**
### Authority required

**Cows' milk anaphylaxis**

- **Population criteria:**
  - Patient must be up to the age of 24 months.

- **Treatment criteria:**
  - Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required

**Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein**

- **Treatment Phase:** Continuing treatment

- **Clinical criteria:**
  - Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

- **Population criteria:**
  - Patient must be up to the age of 24 months.

- **Treatment criteria:**
  - Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Note

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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powder for, 400 g

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required
Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
The condition must not be isolated infant colic or reflux,
AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
The condition must not be isolated infant colic or reflux.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
The condition must not be isolated infant colic or reflux.

Population criteria:
Patient must be older than 24 months of age.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:
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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

**Cows’ milk anaphylaxis**

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist, or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**

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

**Note**

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

**Authority required**

**Cows’ milk protein enteropathy**

**Treatment Phase:** Continuing treatment

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**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Severe cows’ milk protein enteropathy with failure to thrive**

**Treatment Phase:** Continuing treatment

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**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.
The condition must not be isolated infant colic or reflux.

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows’ milk protein enteropathy and intolerance to soy protein
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Treatment Phase: Initial treatment**

Clinical criteria:
The condition must not be isolated infant colic or reflux,

AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**
Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Clinical criteria:
The condition must not be isolated infant colic or reflux,

AND

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

Treatment Phase: Continuing treatment

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Biliary atresia

**Authority required**
Chronic liver failure with fat malabsorption

**Authority required**
Chylous ascites

**Authority required**
Cystic fibrosis

**Authority required**
Enterokinase deficiency

**Authority required**
Proven fat malabsorption

**Authority required**
Severe diarrhoea of greater than 2 weeks duration

Population criteria:
Patient must be aged less than 4 months.

The date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Authority required**
Chylothorax

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

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

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<tr>
<td>2676WNP</td>
<td>PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES</td>
<td>8</td>
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<td>..</td>
<td>*172.28</td>
<td>37.70</td>
<td>Alfaré  NT</td>
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</tbody>
</table>

Cows’ milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Clinical criteria:
The condition must not be isolated infant colic or reflux,

AND
Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.
**Authority required**

**Cows’ milk protein enteropathy and intolerance to soy protein**
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,
AND
Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**

**Cows’ milk protein enteropathy and intolerance to soy protein**
Clinical criteria:
The condition must not be isolated infant colic or reflux,
AND
Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**
Treatment Phase: Initial treatment for up to 6 months

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**
Treatment Phase: Continuing treatment

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Biliary atresia**

**Authority required**
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<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8259Q</td>
<td>protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g</td>
<td>8</td>
<td>5</td>
<td>*110.20</td>
<td>37.70</td>
<td>Karicare Aptamil Pepti-Junior Gold NU</td>
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<tr>
<td>10152H</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
<td>8</td>
<td>5</td>
<td>*421.64</td>
<td>37.70</td>
<td>Monogen SB</td>
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<tr>
<td>10154K</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
<td>8</td>
<td>5</td>
<td>*411.80</td>
<td>37.70</td>
<td>Peptamen Junior NT</td>
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<tr>
<td>10155L</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
<td>8</td>
<td>5</td>
<td>*443.16</td>
<td>37.70</td>
<td>Lipistart VF</td>
</tr>
</tbody>
</table>

**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Note**

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

**Note**

Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.
### Carbohydrates

**AMYLOPECTIN MODIFIED LONG CHAIN**

*Restricted benefit*

Glycogen storage disease

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>9386B</td>
<td>amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets</td>
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<td>5</td>
<td>*752.64</td>
<td>37.70</td>
<td>Glycosade</td>
</tr>
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</table>

### Milk substitutes

**MILK POWDER LACTOSE FREE FORMULA**

*Authority required*

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8282X</td>
<td>milk powder lactose free formula oral liquid: powder for, 900 g</td>
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<td>..</td>
<td>*113.21</td>
<td>37.70</td>
<td>S-26 LF</td>
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<tr>
<td>8283Y</td>
<td>milk powder lactose free formula oral liquid: powder for, 900 g</td>
<td>5</td>
<td>5</td>
<td>*113.21</td>
<td>37.70</td>
<td>S-26 LF</td>
</tr>
</tbody>
</table>

**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

*Authority required*

Acute lactose intolerance

**Population criteria:**

Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2975N</td>
<td>milk powder lactose free formula predigested oral liquid: powder for, 900 g</td>
<td>5</td>
<td>..</td>
<td>*95.76</td>
<td>37.70</td>
<td>Karicare Aptamil Gold De-Lact</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
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</tr>
<tr>
<td>2989H</td>
<td>milk powder lactose free formula predigested oral liquid: powder for, 900 g</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*95.76</td>
<td>37.70</td>
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<tr>
<td>2357C</td>
<td>milk powder lactose modified predigested oral liquid: powder for, 900 g</td>
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<td>10</td>
<td>..</td>
<td>*73.15</td>
<td>37.70</td>
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<tr>
<td>2358D</td>
<td>milk powder lactose modified predigested oral liquid: powder for, 900 g</td>
<td>3</td>
<td>1</td>
<td>..</td>
<td>*73.15</td>
<td>37.70</td>
</tr>
<tr>
<td>3092R</td>
<td>milk powder synthetic low calcium oral liquid: powder for, 400 g</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*381.72</td>
<td>37.70</td>
</tr>
</tbody>
</table>

Clinical criteria:
The condition must be proven to be lactose intolerance.

Population criteria:
Patient must be up to the age of 12 months.
Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

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

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

Note
No applications for increased maximum quantities and/or repeats will be authorised.
No more than 1 application per patient will be authorised.

Other combinations of nutrients

AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit
Pyridoxine non-responsive homocystinuria

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>3417W</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2508.32</td>
<td>37.70</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Dispensed Price for Max. Qty $</td>
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</tr>
<tr>
<td>9330C</td>
<td>docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>4</td>
<td>5</td>
<td>...</td>
<td>*2508.32</td>
<td>TYR Anamix Junior LQ SB</td>
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<tr>
<td>8678R</td>
<td>amino acid formula without phenylalanine 1 g tablet, 75</td>
<td>24</td>
<td>5</td>
<td>...</td>
<td>*1427.32</td>
<td>Phlexy-10 SB</td>
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<tr>
<td>8554F</td>
<td>amino acid formula without phenylalanine 500 mg capsule, 200</td>
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<td>*1276.68</td>
<td>Phlexy-10 SB</td>
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<tr>
<td>2347M</td>
<td>amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets</td>
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<td>*1463.25</td>
<td>Phlexy-10 Drink Mix SB</td>
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<td>10161T</td>
<td>amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets</td>
<td>12</td>
<td>5</td>
<td>...</td>
<td>*3098.68</td>
<td>MSUD amino5 VF</td>
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<tr>
<td>8479G</td>
<td>amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g</td>
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<td>...</td>
<td>*703.96</td>
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<tr>
<td>9438R</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets</td>
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<td>5</td>
<td>...</td>
<td>*2114.72</td>
<td>GA gel VF</td>
</tr>
<tr>
<td>5484P</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets</td>
<td>4</td>
<td>5</td>
<td>...</td>
<td>*3154.76</td>
<td>GA express 15 VF</td>
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<tr>
<td>2650L</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g</td>
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<td>5</td>
<td>...</td>
<td>*769.64</td>
<td>GA1 Anamix infant SB</td>
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<tr>
<td>Code</td>
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<tr>
<td></td>
<td>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN</td>
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<tr>
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<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g</td>
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<td>5</td>
<td>1785.08</td>
<td>37.70</td>
<td>XLYS, LOW TRY Maxamaid SB</td>
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<tr>
<td></td>
<td>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</td>
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<td>1548L</td>
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<td>5</td>
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<td>37.70</td>
<td>HCU Lophlex LQ 20 SB</td>
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<td>9133Q</td>
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<td>5</td>
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<td>37.70</td>
<td>HCU cooler 15 VF</td>
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<tr>
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<td>37.70</td>
<td>HCU cooler 10 VF</td>
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<tr>
<td>8677Q</td>
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<td>5</td>
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<td>37.70</td>
<td>HCU gel VF</td>
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<tr>
<td>8744F</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets</td>
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<td>5</td>
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<td>37.70</td>
<td>HCU express 15 VF</td>
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<tr>
<td>8328H</td>
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<td>37.70</td>
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<td>8416Y</td>
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<td>XMET Maxamum SB</td>
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<tr>
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<td>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE</td>
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<td><strong>Restricted benefit</strong></td>
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<tr>
<td>8417B</td>
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<td>8</td>
<td>5</td>
<td>769.64</td>
<td>37.70</td>
<td>HCU Anamix infant SB</td>
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<tr>
<td></td>
<td>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE</td>
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<tr>
<td>1923F</td>
<td>AMINO ACID FORMULA WITH VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1</td>
<td>4</td>
<td>5</td>
<td>3098.72</td>
<td>37.70</td>
<td>MMA/PA cooler 15 VF</td>
</tr>
<tr>
<td>3444G</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
<td>4</td>
<td>5</td>
<td>2114.72</td>
<td>37.70</td>
<td>MMA/PA gel VF</td>
</tr>
<tr>
<td>3443F</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
<td>4</td>
<td>5</td>
<td>3098.72</td>
<td>37.70</td>
<td>MMA/PA express 15 VF</td>
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**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**

**Restricted benefit**

Maple syrup urine disease

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<th>Max. Qty</th>
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**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCSAHEXAENOIC ACID**

Restricted benefit

Maple syrup urine disease

**ARACHIDONIC ACID AND DOCSAHEXAENOIC ACID WITH CARBOHYDRATE**

Authority required

Peroxisomal biogenesis disorders

**ARGININE WITH CARBOHYDRATE**

Restricted benefit

Urea cycle disorders

Note

Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS**

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.
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<th>Code</th>
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## VARIOUS

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<td>9385Y NP</td>
<td>GLYCINE WITH CARBOHYDRATE Isovaleric acidemia glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets</td>
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<td>5</td>
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<td>5</td>
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<td>*1270.48</td>
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<td>2712R NP</td>
<td>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Phenylketonuria glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g</td>
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<td>5</td>
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<td>*866.78</td>
<td>37.70</td>
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<tr>
<td>2696X NP</td>
<td>HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Ketogenic diet high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 28 x 49 g sachets</td>
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<td>5</td>
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<td>*1037.80</td>
<td>37.70</td>
<td>KetoCal 3:1 SB</td>
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<tr>
<td>658</td>
<td>HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Ketogenic diet high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 28 x 49 g sachets</td>
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<td>5</td>
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<td>37.70</td>
<td>KetoCal 4:1 LQ SB</td>
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<td>2644E NP</td>
<td>Restricted benefit Phenylketonuria glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g</td>
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<td>2685H NP</td>
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<td>*1480.12</td>
<td>37.70</td>
<td>Camino Pro Bettermilk QH</td>
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### Clinical criteria:
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Note**

Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

### Clinical criteria:
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Note**

Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.
### VARIOUS

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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>9446E</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
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<td>*567.32</td>
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<td>9134R</td>
<td>isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
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<td>5</td>
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<td>Isoleucine 50 VF</td>
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<td>soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can</td>
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**HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Restricted benefit**

**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**KetoCal 4:1** should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**

Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**ISOLEUCINE WITH CARBOHYDRATE**

**Restricted benefit**

**MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

**Restricted benefit**

**PHENYLALANINE WITH CARBOHYDRATE**

**Restricted benefit**

**SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

**Restricted benefit**

**Tyrosinaemia**
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<th>Maximum Recordable Value for Safety Net $</th>
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<td>TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER</td>
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<td>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.</td>
<td>9308X</td>
<td>triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans</td>
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<td>9309Y</td>
<td>triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles</td>
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<td>TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER</td>
<td>Restricted benefit</td>
<td>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.</td>
<td>3136C</td>
<td>triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g</td>
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<td>TRIGLYCERIDES MEDIUM CHAIN FORMULA</td>
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<td>9135T</td>
<td>valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets</td>
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Note: No applications for increased maximum quantities and/or repeats will be authorised.

Note: MCT Pro-CaL is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Note: No applications for increased maximum quantities and/or repeats will be authorised.

Note: MCT Pro-CaL is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.
**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

**Authority required**
Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**
Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet,

**AND**
Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**
Patient must be aged 3 years or older.

**Note**
FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

**9328Y**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>NP</td>
<td>vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g</td>
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**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required**
Chronic renal failure

**Clinical criteria:**
Patient must require treatment with a low protein and a low phosphorus diet; OR
Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**Population criteria:**
Patient must be an infant or a young child.

**Note**
Kindergen must only be used under strict supervision of a dietitian and a paediatrician.

**9382T**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>whey protein formula supplemented with amino acids, long chain polysaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets</td>
<td>*1485.91</td>
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**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required**
Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet

**Note**
RenaStart must only be used under strict supervision of a dietitian and a paediatrician.

**2870C**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>NP</td>
<td>whey protein formula supplemented with amino acids, long chain polysaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans</td>
<td>*1584.60</td>
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**8587Y**

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Pharmaceutical Benefits for Palliative Care
### ALIMENTARY TRACT AND METABOLISM

#### STOMATOLOGICAL PREPARATIONS

**Other agents for local oral treatment**

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<td>5385K</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
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<tr>
<td>5386L</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
<td>‡1 ..</td>
<td>22.60</td>
<td>23.75</td>
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<td>Difflam IA</td>
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**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

#### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

**BELLADONNA AND DERIVATIVES, PLAIN**

**Belladonna alkaloids, semisynthetic, quaternary ammonium compounds**

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<td>Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom</td>
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<td>5317W</td>
<td>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
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<tr>
<td>HYOSCINE BUTYLBROMIDE</td>
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<td>Continuing supply for a palliative care patient where colicky pain is a symptom</td>
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<tr>
<td>5318X</td>
<td>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
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#### DRUGS FOR CONSTIPATION

**Contact laxatives**

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<tr>
<td>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem</td>
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<tr>
<td>5303D</td>
<td>bisacodyl 10 mg suppository, 10</td>
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<tr>
<td>5304E</td>
<td>bisacodyl 10 mg suppository, 12</td>
<td>3 3 ..</td>
</tr>
<tr>
<td>5301B</td>
<td>bisacodyl 5 mg tablet: enteric, 200 tablets</td>
<td>1 3 ..</td>
</tr>
</tbody>
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### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tr>
<td>5307H</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>3</td>
<td>..</td>
<td>*21.28</td>
<td>22.43</td>
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<td>Petrus Bisacodyl Suppositories</td>
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<tr>
<td>NP</td>
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<td>5308J</td>
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<td>3</td>
<td>..</td>
<td>*18.67</td>
<td>19.82</td>
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<td>5305F</td>
<td>bisacodyl 5 mg tablet: enteric, 200 tablets</td>
<td>1</td>
<td>..</td>
<td>14.45</td>
<td>15.60</td>
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<td>Bisalax</td>
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</tbody>
</table>

**Bisacodyl**

*Authority required (STREAMLINED)*

3643

Continuing supply for a palliative care patient where constipation is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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</tr>
<tr>
<td>5322D</td>
<td>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
<td>‡1</td>
<td>3</td>
<td>26.71</td>
<td>27.86</td>
<td></td>
<td>Normacol Plus</td>
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<tr>
<td>NP</td>
<td></td>
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</table>

**Rhamnus Frangula + Sterculia**

*Authority required (STREAMLINED)*

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>5324F</td>
<td>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
<td>‡1</td>
<td>..</td>
<td>26.71</td>
<td>27.86</td>
<td></td>
<td>Normacol Plus</td>
</tr>
<tr>
<td>NP</td>
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</table>

**Osmotically acting laxatives**

**Lactulose**

*Authority required (STREAMLINED)*

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

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<thead>
<tr>
<th>Code</th>
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</tr>
<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>3</td>
<td>*18.58</td>
<td>19.73</td>
<td></td>
<td>Genlac</td>
</tr>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QA</td>
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<tr>
<td>5388N</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>..</td>
<td>*18.58</td>
<td>19.73</td>
<td></td>
<td>Genlac</td>
</tr>
<tr>
<td>NP</td>
<td></td>
<td></td>
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<td>QA</td>
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</table>

**Lactulose**

*Authority required (STREAMLINED)*

3643

Continuing supply for a palliative care patient where constipation is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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</tr>
<tr>
<td>5388N</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>..</td>
<td>*21.25</td>
<td>19.73</td>
<td></td>
<td>Actilax</td>
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<tr>
<td>NP</td>
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</tr>
<tr>
<td>5388N</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>..</td>
<td>*21.25</td>
<td>19.73</td>
<td></td>
<td>Actilax</td>
</tr>
<tr>
<td>NP</td>
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</table>

**Macrogol-3350**

*Authority required (STREAMLINED)*

4176

Constipation
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2351R</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>Herron ClearLax ON</td>
</tr>
<tr>
<td>5426N</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>OsmoLax KY</td>
</tr>
</tbody>
</table>

**MACROGOL-3350**  
**Authority required (STREAMLINED)**  

#### Treatment Phase: Initial treatment  
**Clinical criteria:**  
Patient must be receiving palliative care,  
AND  
Patient must not receive more than 4 months treatment under this restriction.  

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2353W</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>Herron ClearLax ON</td>
</tr>
<tr>
<td>5427P</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>OsmoLax KY</td>
</tr>
</tbody>
</table>

**MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE**  
**Authority required (STREAMLINED)**  

#### Treatment Phase: Initial treatment  
**Clinical criteria:**  
Patient must be receiving palliative care,  
AND  
Patient must not receive more than 4 months treatment under this restriction.  

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

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>5389P</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>APO-MACROGOL plus ELECTROLYTES TX</td>
</tr>
<tr>
<td>10127B</td>
<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*22.52</td>
<td>23.67</td>
<td>Movicol Liquid NE</td>
</tr>
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</table>
### Constipation

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must be receiving palliative care.

**Note**
- Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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<tr>
<th>Code</th>
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<tr>
<td>5390Q</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.38</td>
<td>31.53</td>
<td>APO-MACROGOL plus ELECTROLYTES</td>
</tr>
<tr>
<td>10112F</td>
<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*22.52</td>
<td>23.67</td>
<td>LaxaCon</td>
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### Enemas

**BISACODYL**

**Authority required (STREAMLINED)**

3642
- Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

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<tr>
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<tr>
<td>5302C</td>
<td>bisacodyl 10 mg/5 mL enema, 25 x 5 mL</td>
<td>‡1 3</td>
<td>..</td>
<td>38.28</td>
<td>37.70</td>
<td>Bisalax</td>
<td>AS</td>
</tr>
</tbody>
</table>

**BISACODYL**

**Authority required (STREAMLINED)**

3643
- Continuing supply for a palliative care patient where constipation is a problem

**Note**
- Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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<tr>
<td>5306G</td>
<td>bisacodyl 10 mg/5 mL enema, 25 x 5 mL</td>
<td>‡1</td>
<td>..</td>
<td>38.28</td>
<td>37.70</td>
<td>Bisalax</td>
<td>AS</td>
</tr>
</tbody>
</table>

**SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

**Authority required (STREAMLINED)**

3642
- Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

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<tr>
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</thead>
<tbody>
<tr>
<td>5331N</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>2 3</td>
<td>..</td>
<td>*32.62</td>
<td>33.77</td>
<td>Micolette</td>
<td>AE</td>
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</tbody>
</table>

**SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

**Authority required (STREAMLINED)**

3643
- Continuing supply for a palliative care patient where constipation is a problem

**Note**
- Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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</thead>
<tbody>
<tr>
<td>5332P</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>2</td>
<td>..</td>
<td>*32.62</td>
<td>33.77</td>
<td>Micolette</td>
<td>AE</td>
</tr>
</tbody>
</table>
### Peripheral opioid receptor antagonists

**METHYLNALTREXONE**

**Authority required**
Continuing supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has demonstrated a response to methylnaltrexone

**Note**
For first continuing supply, applications for increased repeats may be authorised.

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5424L</td>
<td>METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL</td>
<td>1..</td>
<td>..</td>
<td>288.18</td>
<td>37.70</td>
<td>Relistor</td>
<td>LM</td>
</tr>
</tbody>
</table>

**METHYLNALTREXONE**

**Authority required**
Initial supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has failed to respond to laxatives

**Note**
No applications for repeats will be authorised.

**Note**
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5423K</td>
<td>methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial</td>
<td>3..</td>
<td>..</td>
<td>*130.93</td>
<td>37.70</td>
<td>Relistor</td>
<td>LM</td>
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</tbody>
</table>

### Other drugs for constipation

**GLYCEROL**

**Authority required (STREAMLINED)**
3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

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<tbody>
<tr>
<td>5312N</td>
<td>glycerol 1.4 g suppository, 12</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*21.55</td>
<td>22.70</td>
<td>Petrus Pharmaceuticals Pty Ltd</td>
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<tr>
<td>5313P</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*22.15</td>
<td>23.30</td>
<td>Petrus Pharmaceuticals Pty Ltd</td>
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<tr>
<td>5311M</td>
<td>glycerol 700 mg suppository, 12</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*21.10</td>
<td>22.25</td>
<td>Petrus Pharmaceuticals Pty Ltd</td>
</tr>
</tbody>
</table>

**GLYCEROL**

**Authority required (STREAMLINED)**
3643

Continuing supply for a palliative care patient where constipation is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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# Preparations Which May Be Prescribed for Patients Receiving Palliative Care

## MUSCULO-SKELETAL SYSTEM

### Antiinflammatory and Antirheumatic Products, Non-Steroids

*Acetic acid derivatives and related substances*

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### DICLOFENAC

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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### INDOMETHACIN

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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**Authority required**

Continuing supply for a palliative care patient where severe pain is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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### INDOMETHACIN

**Authority required (STREAMLINED)**

3645

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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**Authority required (STREAMLINED)**

3646

Continuing supply for a palliative care patient where severe pain is a problem

Note

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### Propionic acid derivatives

#### IBUPROFEN

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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**ibuprofen 400 mg tablet, 30**

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**NAPROXEN**

**Authority required (STREAMLINED)**

**3645**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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**NAPROXEN**

**Authority required (STREAMLINED)**

**3646**

Continuing supply for a palliative care patient where severe pain is a problem

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<td>1</td>
<td>..</td>
<td>..</td>
<td>14.30</td>
<td>15.45 a Proxen SR 1000 MD</td>
<td></td>
</tr>
<tr>
<td>5349M</td>
<td>naproxen 250 mg tablet, 50</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*13.68 a Naprosyn SR1000 RO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5350N</td>
<td>naproxen 500 mg tablet, 50</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>*15.92 a Naprosyn RO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5351P</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>12.42</td>
<td>13.57 a Proxen SR 750 MD</td>
<td></td>
</tr>
</tbody>
</table>

**NAPROXEN**

**Authority required (STREAMLINED)**

**4128**

Severe pain

**Clinical criteria:**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent,
- Patient must not receive more than 4 months treatment under this restriction.

**Treatment criteria:**

- Patient must be undergoing palliative care.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5397C</td>
<td>naproxen 125 mg/5 mL oral liquid, 474 mL</td>
<td>‡1</td>
<td>3</td>
<td>..</td>
<td>127.96</td>
<td>37.70</td>
<td>Phebra Naproxen Suspension PL</td>
</tr>
</tbody>
</table>

**NAPROXEN**

**Authority required (STREAMLINED)**

**4129**

Severe pain

**Clinical criteria:**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent,
- Patient must not receive more than 4 months treatment under this restriction.

**Treatment criteria:**

- Patient must be undergoing palliative care.
# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<th>Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>539BD NP</td>
<td>naproxen 125 mg/5 mL oral liquid, 474 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>127.96</td>
<td>37.70</td>
<td>Phebra Naproxen Suspension PL</td>
</tr>
</tbody>
</table>

**NAPROXEN**

Authority required (STREAMLINED)

3645

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

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<tr>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5353R NP</td>
<td>naproxen sodium 550 mg tablet, 50</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>13.11</td>
<td>14.26</td>
<td>a Crysanal MD</td>
</tr>
</tbody>
</table>

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

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<tr>
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<th>Brand Name and Manufacturer</th>
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<td>5354T NP</td>
<td>naproxen sodium 550 mg tablet, 50</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>13.11</td>
<td>14.26</td>
<td>a Crysanal MD</td>
</tr>
</tbody>
</table>

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.
## PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

### NERVOUS SYSTEM

#### ANALGESICS

##### OPIOIDS

**Natural opium alkaloids**

**MORPHINE**

- **Authority required**
- **Initial supply,** for up to 3 months, for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Telephone approvals are limited to 1 month’s therapy.

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<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>5393W</td>
<td>morphine sulfate 10 mg tablet, 20</td>
<td>1</td>
<td>2</td>
<td>14.66</td>
<td>15.81</td>
<td>Sevredol MF</td>
</tr>
<tr>
<td>5394X</td>
<td>morphine sulfate 20 mg tablet, 20</td>
<td>1</td>
<td>2</td>
<td>15.60</td>
<td>16.75</td>
<td>Sevredol MF</td>
</tr>
</tbody>
</table>

**MORPHINE**

- **Authority required**
- **Continuing supply** for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

Telephone approvals are limited to 1 month’s therapy.

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</thead>
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<tr>
<td>5395Y</td>
<td>morphine sulfate 10 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>14.66</td>
<td>15.81</td>
<td>Sevredol MF</td>
</tr>
<tr>
<td>5396B</td>
<td>morphine sulfate 20 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>15.60</td>
<td>16.75</td>
<td>Sevredol MF</td>
</tr>
</tbody>
</table>

**MORPHINE**

- **Authority required**
- **Initial supply,** for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Telephone approvals are limited to 1 month’s therapy.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5391R</td>
<td>morphine sulfate 200 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>2</td>
<td>122.20</td>
<td>37.70</td>
<td>MS Contin MF</td>
</tr>
</tbody>
</table>

**MORPHINE**

- **Authority required**
- **Continuing supply** for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5392T</td>
<td>morphine sulfate 200 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>122.20</td>
<td>37.70</td>
<td>MS Contin MF</td>
</tr>
</tbody>
</table>

#### Phenylpiperidine derivatives

**FENTANYL**

- **Authority required**
- **Breakthrough pain**

---
<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>5411T NP</td>
<td>FENTANYL Lozenge 1200 micrograms (as citrate), 30</td>
<td>2</td>
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<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
<tr>
<td>5412W NP</td>
<td>FENTANYL Lozenge 1600 micrograms (as citrate), 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
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<tr>
<td>5407N NP</td>
<td>FENTANYL Lozenge 200 micrograms (as citrate), 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
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<tr>
<td>5408P NP</td>
<td>FENTANYL Lozenge 400 micrograms (as citrate), 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
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<tr>
<td>5409Q NP</td>
<td>FENTANYL Lozenge 600 micrograms (as citrate), 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
<tr>
<td>5410R NP</td>
<td>FENTANYL Lozenge 800 micrograms (as citrate), 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*579.77</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
</tbody>
</table>

**FENTANYL**

**Authority required**

**Breakthrough pain**

- Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**

- Patient must have cancer,

AND

- Patient must be receiving opioids for their persistent pain,

AND

- Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.

**Treatment criteria:**

- Patient must be undergoing palliative care.

**Caution**

- The risk of drug dependence is high.

**Note**

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

**Note**

- For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<tr>
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<td>FENTANYL Lozenge 1600 micrograms (as citrate), 9</td>
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<td>..</td>
<td>99.95</td>
<td>37.70</td>
<td>Actiq OA</td>
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<tr>
<td>5401G</td>
<td>FENTANYL Lozenge 200 micrograms (as citrate), 9</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>99.95</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
<tr>
<td>5402H</td>
<td>FENTANYL Lozenge 400 micrograms (as citrate), 9</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>99.95</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
<tr>
<td>5403J</td>
<td>FENTANYL Lozenge 600 micrograms (as citrate), 9</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>99.95</td>
<td>37.70</td>
<td>Actiq OA</td>
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<tr>
<td>5404K</td>
<td>FENTANYL Lozenge 800 micrograms (as citrate), 9</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>99.95</td>
<td>37.70</td>
<td>Actiq OA</td>
</tr>
</tbody>
</table>

**Diphenylpropylamine derivatives**

**METHADONE**

**Authority required**

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Telephone approvals are limited to 1 month's therapy.

**Note**

Shared Care Model:

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

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</tr>
</thead>
<tbody>
<tr>
<td>5399E</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>19.25</td>
<td>20.40</td>
<td>Aspen Methadone Syrup QA</td>
</tr>
</tbody>
</table>

**METHADONE**

**Authority required**

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

**Note**

Telephone approvals are limited to 1 month's therapy.

**Note**

Shared Care Model:

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<tbody>
<tr>
<td>5400F</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>19.25</td>
<td>20.40</td>
<td>Aspen Methadone Syrup QA</td>
</tr>
</tbody>
</table>

**OTHER ANALGESICS AND ANTI PYRETICS**

**Anilides**

**PARACETAMOL**

**Authority required (STREAMLINED)**

Initial supply, for up to 4 months, for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

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<tr>
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<tbody>
<tr>
<td>5319Y</td>
<td>paracetamol 500 mg suppository, 24</td>
<td>4</td>
<td>3</td>
<td>..</td>
<td>*84.80</td>
<td>37.70</td>
<td>Panadol GC</td>
</tr>
<tr>
<td>5343F</td>
<td>paracetamol 665 mg tablet: modified release, 96 tablets</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*15.34</td>
<td>16.49</td>
<td>Osteomol 665 Paracetamol CR</td>
</tr>
</tbody>
</table>

**PARACETAMOL**

**Authority required (STREAMLINED)**

Continuing supply for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.
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</tr>
<tr>
<td>5320B</td>
<td>paracetamol 500 mg suppository, 24</td>
<td>4</td>
<td>..</td>
<td>..</td>
<td>84.80</td>
<td>37.70</td>
<td>Panadol</td>
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<td>5344G</td>
<td>paracetamol 665 mg tablet: modified release, 96 tablets</td>
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<td>..</td>
<td>..</td>
<td>15.34</td>
<td>16.49</td>
<td>Osteomol 665 Paracetamol</td>
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<td></td>
<td></td>
<td></td>
<td>GC</td>
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</tbody>
</table>

ANTIEPILEPTICS

ANTIEPILEPTICS

Benzodiazepine derivatives

CLONAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient for the prevention of epilepsy

Note

No applications for increased repeats will be authorised.

5338Y  clonazepam 2 mg tablet, 100  1  3  ..  19.08  20.23  a  Paxam 2  AF
| NP    |                                |                  |             |            |                                 |                                        |                             |
| 5339B  clonazepam 2.5 mg/mL oral liquid, 10 mL  2  3  ..  *15.38  16.53  a  Rivotril  RO
        |                                |                  |             |            |                                 |                                        |                             |
| 5337X  clonazepam 500 microgram tablet, 100  1  3  ..  13.30  14.45  a  Paxam 0.5  AF
        |                                |                  |             |            |                                 |                                        |                             |

CLONAZEPAM

Authority required

Continuing supply for a palliative care patient for the prevention of epilepsy

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

5341D  clonazepam 2 mg tablet, 100  1  ..  ..  19.08  20.23  a  Paxam 2  AF
| NP    |                                |                  |             |            |                                 |                                        |                             |
| 5342E  clonazepam 2.5 mg/mL oral liquid, 10 mL  2  ..  ..  *15.38  16.53  a  Rivotril  RO
        |                                |                  |             |            |                                 |                                        |                             |
| 5340C  clonazepam 500 microgram tablet, 100  1  ..  ..  13.30  14.45  a  Paxam 0.5  AF
        |                                |                  |             |            |                                 |                                        |                             |

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

DIAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

Note

No applications for increased repeats will be authorised.

5355W  diazepam 2 mg tablet, 50  1  3  ..  7.92  9.07  a  Antenex 2  AF
| NP    |                                |                  |             |            |                                 |                                        |                             |
| 5356X  diazepam 5 mg tablet, 50  1  3  ..  8.04  9.19  a  Antenex 5  AF
        |                                |                  |             |            |                                 |                                        |                             |

DIAZEPAM
<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>5357Y</td>
<td>diazepam 2 mg tablet, 50</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>7.92</td>
<td>9.07</td>
<td>Antenex 2</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>APO-Diazepam TX</td>
</tr>
<tr>
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**Hypnotics and Sedatives**

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**Nitrazepam**

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**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.
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**TEMAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem

**Note**

No applications for increased repeats will be authorised.

**TEMAZEPAM**

**Authority required**

Continuing supply for a palliative care patient where insomnia is a problem

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.
Items Available under Special Arrangements (Section 100)
Section 100 – Items Available under Special Arrangement

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

- Highly Specialised Drugs Program
- Botulinum Toxin Program
- Human Growth Hormone Program
- IVF/GIFT Program
- Opiate Dependence Treatment Program

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.
Section 100 – Highly Specialised Drugs Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – In addition to the above requirements, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia’s Authority Freecall service (1800 888 333). Prescribers must quote the provider number of the hospital when applying. Not more than two months’ supply (one month’s supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital’s dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).
BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG
Authority required
Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required
Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required
Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag.

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag.

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

**Note**

No applications for increased repeats will be authorised.
(b) a platelet count of less than or equal to 20,000 million per L; or

(a) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.
Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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</table>

**Note**

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note**

Special Pricing Arrangements apply.

**ANTIANEMIC PREPARATIONS**

### OTHER ANTIANEMIC PREPARATIONS

#### Other antianemic preparations

**DARBEPOETIN ALFA**

*Authority required*

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

<table>
<thead>
<tr>
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<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>6320P</td>
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<td>*377.08</td>
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<td>AN</td>
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<tr>
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<td>6326Y</td>
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<tr>
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**EPOETIN ALFA**

*Authority required*

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

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<td>*2017.06</td>
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<td>JC</td>
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<td>JC</td>
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<td>Code</td>
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<td>*1674.68</td>
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**EPOETIN BETA**

*Authority required*

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

<table>
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<td>NeoRecormon</td>
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<td>5</td>
<td>..</td>
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<td>NeoRecormon</td>
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<td>NeoRecormon</td>
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<td>6482E</td>
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<td>5</td>
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<td>NeoRecormon</td>
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</table>

**EPOETIN LAMBDA**

*Authority required*

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

**Note**

Epoetin lambda should only be administered by the intravenous route.

<table>
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<td>9685R</td>
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<td>*515.94</td>
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<tr>
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**METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**

*Authority required*

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

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<td>5</td>
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<td>*1388.40</td>
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<tr>
<td>Code</td>
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<td>5</td>
<td>..</td>
<td>*938.62</td>
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</tr>
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</table>
CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Other antihypertensives

AMBRISENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be
### Authority required

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Conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

- For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.
- Applications for authority to prescribe should be forwarded to:
  - Department of Human Services
  - Prior Written Approval of Complex Drugs
  - Reply Paid 9826
  - GPO Box 9826
  - HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

i. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
ii. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested. The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Note

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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**Note**
Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Caution**
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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</table>
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved...
The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
For eligible patients, response to treatment is defined as:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, where the total lung capacity is less than 70% of predicted.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and wish to re-commence PBS-subsidised therapy with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised treatment with this agent; OR

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Note

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**BOSENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase**: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient
Highly Specialised Drugs Program (Private Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

Has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function
assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.
## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
<tr>
<th>Code</th>
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</table>

### Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### Authority required

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)**

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised treatment with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that

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patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of...
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

**AND**
Patient must have not responded to prior PBS-subsidised therapy with this agent,

**AND**
The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy,

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Caution**
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**EPOPROSTENOL**

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

**AND**
Patient must have been assessed by a physician at a designated hospital,

**AND**
Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,
AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,
AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,
AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,
AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ Qty</th>
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</tr>
</thead>
</table>

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

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Applications for authority to prescribe should be forwarded to:
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Reply Paid 9826
GPO Box 9826
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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note**
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<tr>
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<th>Brand Name and Manufacturer</th>
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<td>5042J</td>
<td>EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1</td>
<td>77.31 a</td>
<td>Flolan Kit GK</td>
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<td>epoprostenol 500 microgram injection, 1 x 500 microgram vial</td>
<td>43.37 a</td>
<td>Veletri AT</td>
</tr>
</tbody>
</table>

**ILOPROST**

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent,
- Patient must have been assessed by a physician at a designated hospital,
- Patient must have WHO Functional Class III drug-induced PAH,
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the...
following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH; OR
Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
Patient must have WHO Functional Class IV drug-induced PAH,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
Demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

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Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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**Note**

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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**Note**

Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Note**

Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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### MACITENTAN

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase:** Initial 1 (new patients)

**Clinical criteria:**

1. Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,
2. AND
3. Patient must have been assessed by a physician at a designated hospital,
4. AND
5. Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or heritable PAH; OR
6. Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,
7. AND
8. Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
9. Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,
10. AND
11. Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,
12. AND
13. The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. (i) RHC composite assessment; and
   2. (ii) ECHO composite assessment; and
   3. (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the
Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HIGHERLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

*Clinical criteria:*
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,
AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition,

**Authority required**
Pulmonary arterial hypertension (PAH)

*Clinical criteria:*
- Patient must have received approval for initial PBS-subsidised treatment with this agent,
AND
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,
AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND
Patient must have been assessed by a physician at a designated hospital,

AND
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending...
order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Note
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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure
continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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1 .. .. 791.63

a APO-Sildenafil PHT TX

a Sildenafil AN PHT 20 PF

a SILDENAFIL-DRx EA

a Sildenafil Sandoz PHT SZ

TADALAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension,
drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

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Applications for authority to prescribe should be forwarded to:

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**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.
Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
- Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.
AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

**HYPOTHALAMIC HORMONES**

*Somatostatin and analogues*

**LANREOTIDE**

*Authority required*

Acromegaly

Clinical criteria:

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

*Authority required*

Functional carcinoid tumour

Clinical criteria:

The condition must be causing intractable symptoms,

AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,

AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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</table>

**LANREOTIDE**

*Authority required*

Acromegaly

Clinical criteria:

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,
The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

6332G
lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack

**Dispensed Price for Max. Qty**

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<tr>
<td>Somatuline LA IS</td>
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</table>

**OCTREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

The condition must be controlled with octreotide immediate release injections,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

Patient must have achieved symptom control on octreotide immediate release injections,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months’ therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

Patient must have achieved symptom control on octreotide immediate release injections,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months’ therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6426F
octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

**Dispensed Price for Max. Qty**

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6427G
octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

**Dispensed Price for Max. Qty**

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6428H
octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

**Dispensed Price for Max. Qty**

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**OCTREOTIDE**

**Authority required**

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily.

**Authority required**

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**6228T**

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

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**CALCIUM HOMEOSTASIS**

**ANTI-PARATHYROID AGENTS**

*Other anti-parathyroid agents*

**CINACALCET**

**Authority required**

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

**Authority required**

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.

**Note**

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

“Sustained” means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Note**

Special Pricing Arrangements apply.

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## ANTIINFECTIVES FOR SYSTEMIC USE

### ANTIBACTERIALS FOR SYSTEMIC USE

#### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

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#### CLARITHROMYCIN

**Authority required**

Treatment of Mycobacterium avium complex infections

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### ANTIMYCOBACTERIALS

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

#### Antibiotics

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<tr>
<td>738</td>
<td>valaciclovir 500 mg tablet, 100</td>
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### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

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#### GANCICLOVIR

**Authority required**

Cytomegalovirus retinitis in severely immunocompromised patients

**Authority required**

Prophylaxis against cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required**

Prophylaxis against cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

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#### VALACICLOVIR

**Authority required**

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

**Authority required**

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

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</table>

### VALGANCICLOVIR

**Authority required**

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

**Authority required**

Prophylaxis of cytomegalovirus disease in patients at risk of cytomegalovirus disease

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</table>
### Phosphonic acid derivatives

#### FOSCARNET

**Authority required**

Treatment of cytomegalovirus retinitis in patients with AIDS

**Authority required**

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>..</td>
<td>1224.26</td>
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### Protease inhibitors

#### ATAZANAVIR

**Authority required**

HIV infection

**Clinical criteria:**

- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- The treatment must be in combination with other antiretroviral agents.

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<thead>
<tr>
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#### BOCEPREVIR

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

- Patient must have compensated liver disease,
- Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
- The treatment must be in combination with peginterferon alfa and ribavirin,
- The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12.

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#### FOSCARNET

**Authority required**

Treatment of cytomegalovirus retinitis in patients with AIDS

**Authority required**

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

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### Foscarnet

Phosphonic acid derivatives

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### Valganciclovir

Phosphonic acid derivatives

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<th>Max. Qty (Packs)</th>
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#### Valganciclovir

Phosphonic acid derivatives

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### Foscarnet

Phosphonic acid derivatives

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<td>1</td>
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</tbody>
</table>
The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Populate criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.

Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Populate criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.

Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Note

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

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.
## DARUNAVIR

**Authority required**

Treatment of HIV Infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

<table>
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<tr>
<th>Code</th>
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</table>

## FOSAMPRENAVIR

**Authority required**

HIV infection

**Treatment Phase: Initial**

Clinical criteria:

- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>Telzir VI</td>
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</table>

## INDINAVIR

**Authority required**

HIV infection

**Treatment Phase: Initial**

Clinical criteria:
### Code 6202K
**Indinavir 400 mg capsule, 180**
- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Dispensed Price for Max. Qty:** *953.16
- **Brand Name and Manufacturer:** Crizivan 400 mg, MK

**Ritonavir**

### Code 9677H
**Ritonavir 100 mg tablet, 30**
- **Max. Qty (Packs):** 24
- **No. of Rpts:** 5
- **Dispensed Price for Max. Qty:** *1028.92
- **Brand Name and Manufacturer:** Norvir, VE

### Code 6494T
**Ritonavir 600 mg/7.5 mL oral liquid, 90 mL**
- **Max. Qty (Packs):** 10
- **No. of Rpts:** 5
- **Dispensed Price for Max. Qty:** *953.16
- **Brand Name and Manufacturer:** Norvir, VE

**Saquinavir**

### Code 6498B
**Saquinavir 500 mg tablet, 120**
- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Dispensed Price for Max. Qty:** *1057.88
- **Brand Name and Manufacturer:** Invirase, RO

**Simeprevir**

### Code 742
**Simeprevir**
- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Dispensed Price for Max. Qty:** *1053.16
- **Brand Name and Manufacturer:**

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**Highly Specialised Drugs Program (Private Hospital)**

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</tbody>
</table>

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**Patient must be antiretroviral treatment naive,**

**AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

**AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

**AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

**AND**

The treatment must be in combination with other antiretroviral agents.

---

**Simeprevir**

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for hepatitis C infection,

**AND**

The treatment must be in combination with other antiviral agents.
Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

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Note

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

Note

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

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for
hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

10197Q simprevir sodium 150 mg capsule, 7

TELAPREVIR

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**

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**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where
the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

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

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

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

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<th>No. of Rpts</th>
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<td>2378E</td>
<td>telaprevir 375 mg tablet, 42</td>
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<td>..</td>
<td>*14912.50</td>
<td>Incivo</td>
<td>JC</td>
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**Tipranavir**

Authority required
Treatment of HIV Infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note**
Special Pricing Arrangements apply.

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<tr>
<td>9610T</td>
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<td>..</td>
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<td>Aptivus</td>
<td>BY</td>
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**Nucleoside and nucleotide reverse transcriptase inhibitors**

**Abacavir**

Authority required
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive;
AND
The treatment must be in combination with other antiretroviral agents.

Authority required
HIV infection

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection,
AND
The treatment must be in combination with other antiretroviral agents.

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<td>Ziagen</td>
<td>VI</td>
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<td>6264Q</td>
<td>abacavir 300 mg tablet, 60</td>
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<td>..</td>
<td>*593.32</td>
<td>Ziagen</td>
<td>VI</td>
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**Adefovir Dipivoxil**

Authority required
Chronic hepatitis B in a patient without cirrhosis who has failed antiviral therapy and who satisfies all of the following criteria:
(a) Repeatedly elevated serum ALT levels while on concurrent antiviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antiviral therapy except in patients with evidence of poor compliance.

Authority required
Chronic hepatitis B in a patient with cirrhosis who has failed antiviral therapy and who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30...
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**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

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**DIDANOSINE**

**Authority required**

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

---

**EMTRICITABINE**

**Authority required**

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

---

**ENTSCEVIR**

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent anthepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous anthepadnaviral therapy except in patients with evidence of poor compliance

Authority required
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td></td>
<td>Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.</td>
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<td></td>
<td>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.</td>
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<td>Note</td>
<td>PBS-subsidised entecavir monohydrate must be used as monotherapy.</td>
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<tr>
<td>9603K</td>
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**ENTECAVIR**

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   - Confirmed elevated serum ALT;
   - Liver biopsy

**Authority required**

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.

| 9602J | entecavir monohydrate 500 microgram tablet, 30 | 2         | 5           | ..          | 806.10 | Baraclude | BQ |

**LAMIVUDINE**

**Authority required**

HIV infection.

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection.

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

| 6194B | lamivudine 10 mg/mL oral liquid, 240 mL | 8         | 5           | ..          | 472.52 | 3TC | VI |
| 6193Y | lamivudine 150 mg tablet, 60          | 2         | 5           | ..          | 325.70 | 3TC | VI |
| 6435Q | lamivudine 300 mg tablet, 30          | 2         | 5           | ..          | 325.70 | 3TC | VI |

**LAMIVUDINE**

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or
(b) Liver biopsy

**Authority required**

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6257H lamivudine 100 mg tablet, 28

| 2 | 5 | .. | *175.70 | a | Zeffix | AS |

6271C lamivudine 5 mg/mL oral liquid, 240 mL

| 5 | 5 | .. | *242.06 | a | Zetlam | AF |

**STAVUDINE**

**Authority required**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive,
- AND The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- AND The treatment must be in combination with other antiretroviral agents.

6186N stavudine 20 mg capsule, 60

| 2 | 5 | .. | *589.16 | Zerit | BQ |

6189R stavudine 30 mg capsule, 60

| 2 | 5 | .. | *700.82 | Zerit | BQ |

6190T stavudine 40 mg capsule, 60

| 2 | 5 | .. | *932.16 | Zerit | BQ |

**TELBIVUDINE**

**Authority required**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

2. Evidence of chronic liver injury as determined by:
   (a) Confirmed elevated serum ALT; or
   (b) Liver biopsy

**Authority required**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

9630W telbivudine 600 mg tablet, 28

| 2 | 5 | .. | *528.60 | Sebivo | NV |

**TENOFOVIR**

**Authority required**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive,
AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis,

AND

Patient must be nucleoside analogue naïve,

AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection,

AND

Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must have cirrhosis,

AND

Patient must be nucleoside analogue naïve,

AND

Patient must have detectable HBV DNA,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis,

AND

Patient must have failed antihepadnaviral therapy,

AND

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.
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<td><strong>6358P</strong></td>
<td><strong>tenofovir disoproxil fumarate 300 mg tablet, 30</strong></td>
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<td>5</td>
<td>..</td>
<td>*1011.60</td>
<td>Viread</td>
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</tbody>
</table>

**ZIDOVUDINE**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6153W  

zidovudine 100 mg capsule, 100  

4                | 5            | ..     | *861.48    | Retrovir    | VI

6154X  

zidovudine 250 mg capsule, 40  

6                | 5            | ..     | *1279.54   | Retrovir    | VI

6155Y  

zidovudine 50 mg/5 mL oral liquid, 200 mL  

15               | 5            | ..     | *706.96    | Retrovir    | VI

**Non-nucleoside reverse transcriptase inhibitors**

**EFAVIRENZ**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9618F  

efavirenz 200 mg tablet, 90  

2                | 5            | ..     | *571.64    | Stocrin     | MK

6372J  

efavirenz 30 mg/mL oral liquid, 180 mL  

7                | 5            | ..     | *599.87    | Stocrin     | MK

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must have cirrhosis,

AND

Patient must have failed antiviral therapy,

AND

Patient must have detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antiviral agents.
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<td>greater than 400 copies per mL on two consecutive</td>
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<td>emerging signs and symptoms of progressing HIV</td>
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### Treatment Phase: Initial

**Clinical criteria:**
Patient must be antiretroviral treatment naive,

**AND**
The treatment must be in combination with other antiretroviral agents.

**Authority required**
HIV infection

### Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection,

**AND**
The treatment must be in combination with other antiretroviral agents.

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### Antivirals for treatment of HIV infections, combinations

#### ABACAVIR + LAMIVUDINE

**Authority required**
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive,

**AND**
The treatment must be in combination with other antiretroviral agents.

**Population criteria:**
Patient must be aged 12 years or older,

**AND**
Patient must weigh 40 kg or more.

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#### ABACAVIR + LAMIVUDINE + ZIDOVUDINE

**Authority required**
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive.

**Population criteria:**
Patient must be aged 12 years or older,

**AND**
Patient must weigh 40 kg or more.
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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### Authority required

### LAMIVUDINE + ZIDOVUDINE

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

**AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**
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**RALTEGRAVIR**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

**Population criteria:**

Patient must be aged 2 years or older.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

Patient must be aged 2 years or older.

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**RALTEGRAVIR**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

<table>
<thead>
<tr>
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HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)
ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

AZACITIDINE

Authority required

Initial PBS-subsidised treatment of a patient with:

1. Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
2. Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
3. Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
(c) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(d) a copy of the full blood examination report; and
(e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(f) a signed patient acknowledgment form.

No more than three cycles will be authorised

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Special Pricing Arrangements apply.

6100C azacitidine 100 mg injection, 1 x 100 mg vial 14 2 .. *7746.80 Vidaza CJ
(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Up to six cycles will be authorised

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

6138C  azacitidine 100 mg injection, 1 x 100 mg vial  14  5  ..  *7746.80  Vidaza  CJ

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required
Treatment of AIDS-related Kaposi’s sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

Authority required
Treatment of AIDS-related Kaposi’s sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

6249X  doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial  4  5  ..  *2140.00  a  Caelyx  JC  

a  Liposomal Doxorubicin

OTHER ANTI NEOPLASTIC AGENTS

Monoclonal antibodies

ALEMTUZUMAB

Authority required
Multiple sclerosis
Treatment Phase: Initial

Clinical criteria:
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
The treatment must be as monotherapy,

AND
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND
Patient must be ambulatory (without assistance or support).

Treatment criteria:
Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>10243D</td>
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**AEMTUZUMAB**

**Authority required**

Multiple sclerosis

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not show continuing progression of disability while on treatment with this drug,

AND

Patient must not receive more than one PBS-subsidised treatment per year,

AND

The treatment must be as monotherapy,

AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

Must be treated by a neurologist.

**Note**

Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Special Pricing Arrangements apply.**

**Note**

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

**Note**

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

<table>
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**FILGRASSTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with
readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required**
A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required**
A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

**Authority required**
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

**Authority required**
A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

**Authority required**
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (first-line chemotherapy with escalated BEACOPP)

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### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>*3466.38</td>
<td>Neupogen AN</td>
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**LENOGRASTIM**

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablatative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors.

**Authority required**

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation.

**Authority required**

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

**Authority required**

Patients receiving first-line chemotherapy for Hodgkin’s disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin’s disease.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing’s sarcoma.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin’s lymphoma (intermediate or high grade).

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.
# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>Granocyte 34</td>
<td>HH</td>
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**PEGFILGRASTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient with inoperable Stage III, IVA or IVB squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

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**Interferons**

**INTERFERON ALFA-2A**

**Authority required**
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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<td><strong>Authority required</strong></td>
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<td>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:</td>
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<td>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;</td>
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<td>(2) Evidence of chronic liver injury as determined by:</td>
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<td>(a) Confirmed elevated serum ALT; or</td>
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<td>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.</td>
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<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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<td>Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.</td>
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<td>Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement</td>
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<td>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;</td>
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<td>(2) Evidence of chronic liver injury as determined by:</td>
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<td>(a) Confirmed elevated serum ALT; or</td>
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<td>Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents</td>
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**PEGINTERFERON ALFA-2A**

**Authority required**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy;
3. Has received no prior peginterferon alfa therapy for the treatment of hepatitis B

**Authority required**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

**Authority required**

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

1. Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
2. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop

**Caution**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

a. a nurse educator/counsellor for patients; and
b. 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

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**PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir.

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12;
The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

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

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA quantitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 12,
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

**Chronic non-genotype 1 hepatitis C infection**

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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<th>Max. Qty</th>
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**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Caution**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Caution**

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.
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<th>Code</th>
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<th>Max. Qty (Packs)</th>
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**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

**Population criteria:**

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be
using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,
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**AND**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must weigh at least 27 kg,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

**AND**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with
boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

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

Note

No increase in the maximum number of repeats may be authorised.
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

**AND**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection
### Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

### Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

### Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

### Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

### Caution

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

### Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

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<td>5</td>
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</table>
PEGINTERFERON ALFA-2B (&) RIBAVIRIN

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

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

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

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required
Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative...
assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

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

**Note**

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

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,
AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

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

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

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND
Patient must have compensated liver disease,

AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older,

AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Caution
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.
Caution
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Other immunostimulants
PLERIXAFOR
Authority required
Mobilisation of haematopoietic stem cells

Clinical criteria:
The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF),
AND
Patient must have lymphoma; OR
Patient must have multiple myeloma,
AND
Patient must require autologous stem cell transplantation,
AND
Patient must have failed previous stem cell collection; OR
Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

Note
Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.
Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily or; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have...
failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Applications for initial treatment should be made where:

(a) initial treatment.

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab [Initial 1]; or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months [Initial 1]; or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent [Initial 2] (further details are under ‘Swapping therapy’ below); or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent [Initial 2].

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

- Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
- A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

**AND**

Patient must have demonstrated an adequate response to treatment with this drug.
AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment.

AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDS) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
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**ECULIZUMAB**

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 - New patient

**Clinical criteria:**

Patient must have active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L,

AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days,

AND

Patient must have clinical features of active organ damage or impairment,

AND

Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L ; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form- Initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
ECULIZUMAB

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 - New patient - Balance of Supply

**Clinical criteria:**

Patient must have received PBS-subsidised initial supply of eculizumab for this condition,

**AND**

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample,

**AND**

Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.
ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

**Note**

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

**Note**

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

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**ECULIZUMAB**

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – New patient

**Clinical criteria:**

Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition,

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or
PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note
WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – beyond initial 48 weeks of treatment

Clinical criteria:
Patient must have received 48 weeks of treatment under Initial treatment-New patient, Initial treatment-Balance of supply and Continuing treatment-New patient with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition,

AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min),

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(6) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(7) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(8) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note
WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recomencement of treatment after an initial 48-week period

Clinical criteria:
Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition,

AND
Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND
Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR(iii) TMA-related organ impairment including on recent biopsy, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or
### PBS-subsidised treatment with eculizumab

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

1. dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

1. A completed authority prescription form(s); and

2. A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2- Recommencement of treatment after an initial 48-week period; and

3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

4. A copy of a current Certificate of vaccination; and

5. A measurement of body weight at the time of application, and

6. A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

7. Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

8. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

9. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note**

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**

A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note**

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

**Note**

**WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Note**

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Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

**Clinical criteria:**

Patient must have received initial treatment 2-recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition,

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:

   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

   b) an eGFR within +/- 25% from baseline; or

   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

1. A completed authority prescription form; and

2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

3. A copy of a current Certificate of vaccination; and

4. A measurement of body weight at the time of application; and

5. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application ; and
(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note**
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**
WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial 3 - Grandfather eculizumab patients

**Clinical criteria:**

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS,

AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014,

AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application,

AND

Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response,

AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition,

AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:
(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;
(ii) low or absent haptoglobin;
(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and

(7) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(10) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and

(11) Where available in the week prior to commencing eculizumab results demonstrating:

(a) a platelet count of less than 150 x10^9/L ; and evidence of two of the following:
   (i) presence of schistocytes on blood film;
   (ii) low or absent haptoglobin;
   (iii) lactate dehydrogenase (LDH) above normal range;
   OR
   (b) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

AND

(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:
   (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
   (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   (iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or
   (iv) a renal biopsy
   (b) onset of TMA-related neurological impairment;
   (c) onset of TMA-related cardiac impairment;
   (d) onset of TMA-related gastrointestinal impairment;
   (e) onset of TMA-related pulmonary impairment ; and

(12) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

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

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Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

10194M  eculizumab 300 mg/30 mL injection, 1 x 30 mL vial 1 5 .. 5984.26 Soliris XI

EVEROLIMUS

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**MYCOPHENOLATE**

**Authority required**
Prophylaxis of renal allograft rejection
Treatment Phase: Management

**Clinical criteria:**
The treatment must be under the supervision and direction of a transplant unit.

**Authority required**
WHO Class III, IV or V lupus nephritis
Treatment Phase: Management

**Clinical criteria:**
The condition must be proven by biopsy.

**Treatment criteria:**
Must be treated by a nephrologist or in consultation with a nephrologist.
The name of the consulting nephrologist must be included in the patient medical records.

**Caution**
Careful monitoring of patients is mandatory.

**Note**
Management includes initiation, stabilisation and review of therapy as required.

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**MYCOPHENOLATE**

**Authority required**
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Authority required**
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**
Careful monitoring of patients is mandatory.

**Note**
For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

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**MYCOPHENOLATE**

**Authority required**
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Authority required**
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required
**Caution**

Careful monitoring of patients is mandatory.

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**NATALIZUMAB**

**Authority required**

Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

**Authority required**

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.

**Caution**

Progressive multifocal leukoencephalopathy has been reported with this drug.

**Note**

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Note**

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Manufacturer</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty</th>
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**SIROLIMUS**

**Authority required**

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

**Caution**

Careful monitoring of patients is mandatory.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Manufacturer</th>
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**Tumor necrosis factor alpha (TNF-) inhibitors**

**ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition;

OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

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

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to
treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commencement a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment;

**And**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

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A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in PBS-subsidised therapy of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
**HIGHLY SPECIALISED DRUGS PROGRAM** (Private Hospital)

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</tr>
</tbody>
</table>

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**ETANERCEPT**

**Authority required**

Severe active juvenile idiopathic arthritis
TREATMENT PHASE: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

1) a completed authority prescription form; and
2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a new bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a new bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of...
treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must
commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Clinical criteria:
Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more
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than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of
Treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, or on after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have...
failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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### INFLIXIMAB

**Authority required**

Acute severe ulcerative colitis

**Clinical criteria:**

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application,

AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below,

AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient’s medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

**Note**

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

### INFLIXIMAB

**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase: Initial treatment (new patient)**

**Clinical criteria:**
Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal.

AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal.

AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient’s condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or PUCAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)

Clinical criteria:
Patient must have been receiving treatment with this drug prior to 1 December 2014,

AND
Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR
Patient must have had a partial Mayo clinic score greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 10 prior to commencing treatment with this drug; OR
Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available,

AND
Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 1, with no subscore greater than or equal to 0.5 while receiving treatment with this drug; OR
Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 0.5 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:
Patient must be 6 years of age or older.

Treatment criteria:
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition and
(ii) the date of commencement of this drug and
(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

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

Note
Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
MODERATE TO SEVERE ULCERATIVE COLITIS

Treatment Phase: Balance of Supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients).

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

**Note**

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a...
consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

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

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Special Pricing Arrangements apply.

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**INFLIXIMAB**

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**
Patient must have severe active rheumatoid arthritis,

**AND**
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

**AND**
Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

**AND**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

**AND**
Patient must not receive more than 22 weeks of treatment under this restriction,
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to try 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  1. a total active joint count of at least 20 active (swollen and tender) joints; or
  2. at least 4 active joints from the following list of major joints:
     - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

For second and subsequent courses of PBS-subsidised bDMARDs, patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that bDMARD. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis,
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,
- Patient must not receive more than 22 weeks of treatment under this restriction,
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARDs must requalify for treatment under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months may apply for a further course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 2 weeks prior to the patient completing their current treatment course must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Abatacept patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first treatment of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients switching from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment,

AND
The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis,

AND
Patient must have demonstrated an adequate response to treatment with infliximab,

AND
Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD. If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with infliximab.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
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Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and has who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with...
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
INFLIXIMAB

Authority required
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,
AND
Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,
AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurement parts of the Bath Ankylosing Spondylitis Metrology Index (BASM); or (iii) limitation of chest expansion relative to normal values for age and gender,
AND
Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 4 months old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy)
the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this
Where a response assessment is not submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:

Department of Human Services
**Prior Written Approval of Complex Drugs**

Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis,
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.
- An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
  - an ESR measurement no greater than 25 mm per hour; or
  - a CRP measurement no greater than 10 mg per L; or
  - an ESR or CRP measurement reduced by at least 20% from baseline.
- Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
- The authority application must be made in writing and must include:
  - a completed authority prescription form; and
  - a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
- All measurements provided must be no more than 1 month old at the time of application.
- A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to every course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who has received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
**INFLIXIMAB**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

- Patient must have severe active psoriatic arthritis,
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a
The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note**
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

**AND**
Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

**AND**
Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

**AND**
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

**AND**
Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     i. elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     ii. shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a
particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to continuing treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment,

AND
The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

AND
Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND
Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are...
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-treat this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply
### Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

### Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

#### INFILIXIMAB

**Authority required**

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's
Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE be consultant physicians [general medicine specialising in gastroenterology (code 81)] or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less. Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition.

The PCDAI assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) Authority required

Initial PBS-subsidised treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) Authority required

Initial PBS-subsidised treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the
restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

INFLIXIMAB
Authority required
Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

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(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for authorisation must be made in writing and must include:

- recent prior treatment.
- To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist assessed by consultant physicians [general medicine specialising in gastroenterology (code 82)].
- If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.
- NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form;
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient’s condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist assessed within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Consultant physicians [general medicine specialising in gastroenterology (code 82)].

The CDAI assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

-...
Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Authority required
Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:
   — azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
   — 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
   — methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have evidence of intestinal inflammation, including:
   (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
   (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
   (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR
   (b) be assessed clinically as being in a high faecal output state;
   (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
   (iii) date of the most recent clinical assessment; and
   (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Highly Specialised Drugs Program (Private Hospital)**
To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timesframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient’s assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR

(c) be assessed clinically as being in a high faecal output state; AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) which includes the following:
   (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
   (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient’s condition, if relevant; and
   (iii) date of the most recent clinical assessment; and
   (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to the initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:
   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
   (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
   (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
   (c) reversal of high faecal output state; or
   (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) which includes the following:

   (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the dates of assessment of the patient’s condition; or
   (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
   (iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.
At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

**Initial 3 (grandfather)**

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed PBS Authority Form - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient’s condition; or
(ii) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(iii) clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient’s assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 3).

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

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

INFLIXIMAB

Authority required

Initial treatment [Initial 1, Whole body [New patients — No prior biological agent]]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
   (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
   (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
   (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
   (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Applications for authorisation must be made in writing and must include:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

**Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]**

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised treatment with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

**Continuing treatment (Whole body)**

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.
An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and  
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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**Highly Specialised Drugs Program (Private Hospital)**
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.
A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction. (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’

### Continuing PBS Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’
From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]: or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within
Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**
No applications for increased repeats will be authorised.

**INFLIXIMAB**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**Note**: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Initial 2
Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1900 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction only once Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1900 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826
How to prescribe PBS-

There is no limit to the number of treatment cycles a patient may undertake in their lifetime. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.
A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Interleukin inhibitors

**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.
**Population criteria:**
Patient must be aged 18 years or older.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note**
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
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<tr>
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</tr>
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</table>

failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

Note
A patient must be assessed for response to any course of initial PBS-subsidised bDMARD treatment of at least 24 months immediately prior to making a new application, or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity [joint count and ESR/CRP] or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

**Authority required**
Severe active juvenile idiopathic arthritis
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used.
The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 3 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD therapy

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD therapy...
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this must be assessed with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

(i) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**
Severe active juvenile idiopathic arthritis

**Clinical criteria:**
Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND
Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND
Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle.

AND
Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
Patient must be under 18 years of age.

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

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be de
assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
that agent (Initial 2).
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further
details are under ‘Swapping therapy’ below]; or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single
treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further
PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised
bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an
alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a
patient may:
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may
commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must
commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further
details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that
agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this
assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing
their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient
completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing
treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab
for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab,
etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an
alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a
patient may:

HIGHERLY SPECIALISED DRUGS PROGRAM (Private Hospital)
bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

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

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<th>No. of Rpts</th>
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(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to co.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   i. the date of assessment of severe active systemic juvenile idiopathic arthritis;
   ii. details of prior treatment including dose and duration of treatment;
   iii. pathology reports detailing CRP and platelet count where appropriate; and
3. a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Authority required
Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; and

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Authority required

Initial 3 (‘grandfather’ patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a
maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:
   (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
   (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
       — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
       — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:
   (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR
   (ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR
   (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Note**

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

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-
rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must qualify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 12 month break in PBS-subsidised therapy’ above for further details.
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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#### TOCILIZUMAB

**Authority required**

Severe active rheumatoid arthritis

#### Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or
The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMDAR trial, but prior to ceasing DMDAR therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains...
Patient may trial an alternate bDMARD at any time, regardless of whether the
requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the
time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist
treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are
assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period
applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated
a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following
patients who have demonstrated a response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority
prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements
of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline
measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response
according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment
with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP
level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint
count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of
active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major
joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still
on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients
must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD
therapy.
**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis,

**AND**
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are
eligible to receive further bDMARD therapy.

**AND**
Patient must not receive more than 16 weeks of treatment under this restriction.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or
tocilizumab.
The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.
All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD treatment, and that an application is submitted to the Department of Human Services no later than 4 weeks from the date that co-supply was ceased.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from...
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD agent.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
## Calcineurin inhibitors

### CYCLOSPORIN

**Authority required**
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Authority required**
Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

**Authority required**
Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

**Authority required**
Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

**Authority required**
Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

**Caution**
Careful monitoring of patients is mandatory.

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### CYCLOSPORIN

**Authority required**
For use by organ or tissue transplant recipients

**Caution**
Careful monitoring of patients is mandatory.

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### TACROLIMUS

**Authority required**
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Caution**
Careful monitoring of patients is mandatory.

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**Other immunosuppressants**

**LENALIDOMIDE**

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

The treatment must be limited to a maximum duration of 16 weeks,

AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR

2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR

3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR

4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR

5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR

6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR

7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome,

AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide,

AND

Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note
Written applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Special Pricing Arrangements apply.

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LENALIDOMIDE

Authority required
Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment
Clinical criteria:

The condition must be confirmed by a histological diagnosis, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone, AND

Patient must have progressive disease after at least one prior therapy, AND

Patient must have undergone or be ineligible for a primary stem cell transplant, AND

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, AND

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or
(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

**Department of Human Services**

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received an authority prescription for lenalidomide,

AND

- Patient must not have progressive disease,

AND

- The treatment must be as monotherapy; OR

- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe should be forwarded to:

**Department of Human Services**

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.
RITUXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and
It is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 24 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘TNF’ alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Special Pricing Arrangements apply.

**Note**

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin–6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 3 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:

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TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin–6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised bDMARD therapy.
date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist...
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

### THALIDOMIDE

**Authority required**

Multiple myeloma

**Caution**

Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note**

Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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## MUSCULO-SKELETAL SYSTEM

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

**BACLOFEN**

*Authority required*

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

*Authority required*

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

*Authority required*

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

*Authority required*

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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### DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

**IBANDRONIC ACID**

*Authority required*

Bone metastases from breast cancer

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>9619G</td>
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</table>

**PAMIDRONATE DISODIUM**

*Authority required*

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>6288Y</td>
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**PAMIDRONATE DISODIUM**

*Authority required*

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</table>

**Hypercalcaemia of malignancy**

**Clinical criteria:**

Patient must have a malignancy refractory to anti-neoplastic therapy.

**Authority required**

Multiple myeloma

**Authority required**

Bone metastases

**Clinical criteria:**

The condition must be due to breast cancer.

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for i.v. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.

**ZOLEDRONIC ACID**

**Authority required**

Multiple myeloma

**Authority required**

Bone metastases from breast cancer

**Authority required**

Bone metastases from castration-resistant prostate cancer

**Authority required**

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Special Pricing Arrangements apply.
## NERVOUS SYSTEM

### ANTI-PARKINSON DRUGS

#### DOPAMINERGIC AGENTS

**Dopa and dopa derivatives**

- **LEVDOPA + CARBIDOPA ANHYDROUS**
  - **Authority required**
  - Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

  - **Note**
  - Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

  - A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

  - **9744W**
    - levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags
    - **Max. Qty (Packs):** 8
    - **No. of Rpts:** 5
    - **Dispensed Price for Max. Qty:** $11582.76
    - **Brand Name and Manufacturer:** Duodopa VE

**Dopamine agonists**

- **APOMORPHINE**
  - **Authority required**
  - Parkinson disease

  - **Clinical criteria:**
  - Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

  - **9607P**
    - apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
    - **Max. Qty (Packs):** 72
    - **No. of Rpts:** 5
    - **Dispensed Price for Max. Qty:** $7243.48
    - **Brand Name and Manufacturer:** Apomine HH

  - **9640J**
    - apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules
    - **Max. Qty (Packs):** 36
    - **No. of Rpts:** 5
    - **Dispensed Price for Max. Qty:** $9050.32
    - **Brand Name and Manufacturer:** Apomine HH

  - **9647R**
    - apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes
    - **Max. Qty (Packs):** 36
    - **No. of Rpts:** 5
    - **Dispensed Price for Max. Qty:** $7054.12
    - **Brand Name and Manufacturer:** Apomine PFS HH

### PSYCHOLEPTICS

#### ANTIPSYCHOTICS

**Diazepines, oxazepines, thiazepines and oxepines**

- **CLOZAPINE**
  - **Authority required**
  - Schizophrenia

  - **Clinical criteria:**
  - Patient must be non-responsive to other neuroleptic agents; OR
  - Patient must be intolerant of other neuroleptic agents.

  - A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

  - **Note**
  - Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program: Novartis Clozaril Patient Monitoring System (CPMPlus) or Clopineconnect.

  - **6102E**
    - clozapine 100 mg tablet, 100
    - **Max. Qty (Packs):** 2
    - **No. of Rpts:** ..
    - **Dispensed Price for Max. Qty:** *258.84
    - **Brand Name and Manufacturer:** Clopine 100 HH

  - **6418T**
    - clozapine 200 mg tablet, 100
    - **Max. Qty (Packs):** 2
    - **No. of Rpts:** ..
    - **Dispensed Price for Max. Qty:** *510.92
    - **Brand Name and Manufacturer:** Clopiner Suspension HH

  - **6101D**
    - clozapine 25 mg tablet, 100
    - **Max. Qty (Packs):** 2
    - **No. of Rpts:** ..
    - **Dispensed Price for Max. Qty:** *75.40
    - **Brand Name and Manufacturer:** Clopine 25 HH

  - **6417R**
    - clozapine 50 mg tablet, 100
    - **Max. Qty (Packs):** 2
    - **No. of Rpts:** ..
    - **Dispensed Price for Max. Qty:** *141.22
    - **Brand Name and Manufacturer:** Cloparin 50 HH

  - **9632Y**
    - clozapine 50 mg/mL oral liquid, 100 mL
    - **Max. Qty (Packs):** 1
    - **No. of Rpts:** ..
    - **Dispensed Price for Max. Qty:** 147.16
    - **Brand Name and Manufacturer:** Clopinel Suspension HH
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation’s experienced while on oral corticosteroids (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer...
Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a documented history of severe allergic asthma; and

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phaun@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician
The assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient’s continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to responding to treatment with omalizumab.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab.  However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab.  However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire [ACQ-5] score, and relevant exacerbation history).  Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once.  A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

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COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight, AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks’ duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND
(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that there agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

Authority required
### Cystic Fibrosis

**Clinical criteria:**
- Patient must have frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year;
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan;
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines;
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**
- Patient must be less than 5 years of age.
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.
- Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required**
- Cystic fibrosis

### Authority required
- Cystic fibrosis

### Clinical criteria:
- Patient must have initiated treatment with dornase alfa at an age of less than 5 years,

**AND**
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**
- Patient must be 5 years of age or older.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required**
- Cystic fibrosis

### Clinical criteria:
- Patient must have initiated treatment with dornase alfa prior to 1 November 2009,

**AND**
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**
- Patient must be less than 5 years of age.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**
- Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note**
- It is highly desirable that all patients be included in the national cystic fibrosis patient database.

### Authority required
- Cystic fibrosis

### Clinical criteria:
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol,
AND

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height.

AND

Patient must be intolerant or inadequately responsive to dornase alfa.

AND

Patient must have evidence of chronic supplicative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND

(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

Authority required
Cystic fibrosis

Clinical criteria:

Patient must have initiated treatment with mannitol prior to 1 August 2012.

AND

Patient must have undergone a comprehensive assessment involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

Population criteria:

Patient must be 6 years of age or older.

Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note
Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

Note
It is highly desirable that all patients be included in the national cystic fibrosis patient database.

2008Q

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OTHER RESPIRATORY SYSTEM PRODUCTS

IVACAFTOR

Authority required
Cystic fibrosis
### Treatment Phase: Initial treatment – New patients

**Clinical criteria:**

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit;

**AND**

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele;

**AND**

Patient must not receive more than 24 weeks of treatment under this restriction;

**AND**

The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, liraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- **Strong CYP3A4 inducers:** aminosalicylate, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort
- **Moderate CYP3A4 inducers:** bosentan, efavirenz, etravirine, modafinil, nafcinil
- **Weak CYP3A4 inducers:** armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
3. a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
5. the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
6. evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and
7. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
8. a copy of a sweat chloride result; and
9. height and weight measurements at the time of application; and
10. a baseline measurement of the number of days of hospitalisation (including hospital-in-the-home) in the previous 12 months.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit;

**AND**

Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition;

**AND**

Patient must not receive more than 24 weeks of treatment under this restriction.
The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, liraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampcin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcinil

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
3. the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
4. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
5. a recent sweat chloride result; and
6. height and weight measurements at the time of application; and
7. a measurement of number of days of hospitalisation (including hospital in the home) in the previous 6 months.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014,

AND

Patient must have received treatment with ivacaftor within the last 6 months at the time of application,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, liraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.
drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and
(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and
(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and
(11) height and weight measurements at the time of application; and
(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and
(13) a baseline measurement of number of days of hospitalisation (including hospital-in-the-home) in the 12 months prior to commencement of ivacaftor; and
(14) a measurement of the number of days of hospitalisation (including hospital-in-the-home) in the 6 months prior to the date of application; and
(15) dates of prior ivacaftor therapy.

Note
Special Pricing Arrangements apply.

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

10175M ivacaftor 150 mg tablet, 56 1 5 .. 22546.76 Kalydeco VR
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority required

Chronic iron overload in patients with disorders of erythropoiesis

Note

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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<th>Dispensed</th>
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DEFERIPRONE

Authority required

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

Authority required

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of</th>
<th>Premium</th>
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DESFERRIOXAMINE

Authority required

Disorders of erythropoiesis associated with treatment-related chronic iron overload

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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<td>5</td>
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<td>*2921.16</td>
<td>Hospira Pty Limited HH</td>
</tr>
</tbody>
</table>

LANTHANUM

Authority required

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:
The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of</th>
<th>Premium</th>
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<th>Brand Name and Manufacturer</th>
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<td>9637F</td>
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<td>Fosrenol ZI</td>
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<td>Fosrenol ZI</td>
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</table>
### SEVELAMER

**Authority required**

Hyperphosphataemia

**Treatment Phase: Initiation and stabilisation**

**Clinical criteria:**

- The condition must not be adequately controlled by calcium,
- AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,
- AND
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium Qty</th>
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</table>

### SUCROFERRIC OXYHYDROXIDE

**Authority required**

Hyperphosphataemia

**Treatment Phase: Initiation and stabilisation**

**Clinical criteria:**

- The condition must not be adequately controlled by calcium,
- AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,
- AND
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tr>
<td>10230K</td>
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</table>
BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

1. Spleenectomised and:
   a. has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
   b. has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
   OR
2. Not spleenectomised and:
   a. has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
   b. has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
   c. in whom splenectomy is contraindicated for medical reasons.

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

1. a platelet count of less than or equal to 20,000 million per L;
   OR
2. a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
4. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Note

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

Note

No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>5</td>
<td>..</td>
<td>3024.00</td>
<td>Revolade</td>
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</table>
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

1. Splenectomised and:
   a. has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
   b. has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy; OR
2. Not splenectomised and:
   a. has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
   b. has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
   c. in whom splenectomy is contraindicated for medical reasons.

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

1. a platelet count of less than or equal to 20,000 million per L; OR
2. a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
4. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.
Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

**Continuing therapy or re-initiation after a break in therapy**

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

1. a completed authority prescription form, and
2. a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
3. copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

**Second and subsequent applications for continuing therapy**

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing treatment may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
### ANTIANEMIC PREPARATIONS

#### OTHER ANTIANEMIC PREPARATIONS

**Other anemic preparations**

**DARBEPOETIN ALFA**

**Authority required (STREAMLINED)**

**3334**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
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**EPOETIN ALFA**

**Authority required (STREAMLINED)**

**3334**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

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<tr>
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<th>Brand Name and Manufacturer</th>
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<td>Eprex 10000 JC</td>
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</table>

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note**

Special Pricing Arrangements apply.
<table>
<thead>
<tr>
<th>Code</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>*1057.34</td>
<td>Eprex 5000 JC</td>
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<td>..</td>
<td>*1255.14</td>
<td>Eprex 6000 JC</td>
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<tr>
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<td>*1627.92</td>
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</table>

**EPOETIN BETA**

*Authority required (STREAMLINED)*

**EPOETIN LAMBDA**

*Authority required (STREAMLINED)*

**METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**

*Authority required (STREAMLINED)*

Note: Epoetin lambda should only be administered by the intravenous route.
<table>
<thead>
<tr>
<th>Code</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>..</td>
<td>*896.02</td>
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</table>

**Note:** The above table lists highly specialised drugs with their codes, names, restrictions, manner of administration, forms, maximum quantity, number of reports, premium, dispensed price for maximum quantity, and brand name and manufacturer. The prices are marked with an asterisk (*) and the currency is unspecified but likely in Australian dollars (A$). The codes are prefixed with '5797', '5798', '5799', '5794', '5800', '5795', and '5796'.
ANTIHYPERTENSIVES

**Other antihypertensives**

**AMBRISENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be
conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,
The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

i. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
ii. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

- The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.
- Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
  1. RHC plus ECHO composite assessments;
  2. RHC composite assessment plus 6MWT;
  3. RHC composite assessment only.
- In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
  1. ECHO composite assessment plus 6MWT;
  2. ECHO composite assessment only.
- Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.
- The test results provided must not be more than 2 months old at the time of application.
- The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
- A maximum of 5 repeats may be requested.
- The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
- Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
- PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
### Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. The results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

### Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

### Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
Pulmonary arterial hypertension (PAH)

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition,
- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Pulmonary arterial hypertension (PAH)

Clinical criteria:

- Patient must have received approval for initial PBS-subsidised treatment with this agent,
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved
based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. PAH agents are not PBS-subsidised therapy with this agent.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease Product Information, and a maximum of 4 repeats.

Approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

<table>
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**BOSENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient
has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function
Highly Specialised Drugs Program (Public Hospital)

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Assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. Two completed authority prescription forms; and

2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

   i. RHC composite assessment; and
   
   ii. ECHO composite assessment; and
   
   iii. 6 Minute Walk Test (6MWT); and

3. A signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) Mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) Where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments; and

2. RHC composite assessment plus 6MWT; and

3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT; and

2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised treatment with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that
patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the
time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be
submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should
be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to
demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-
subsidised treatment with the drug they are ceasing.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270
(hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the
approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the
patient.

**Note**

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or
remaining repeats, for the treatment the patient is ceasing.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all
patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of
treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of
reatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients)
restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of
six months of treatment,

**AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition,

**AND**

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270
(hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Authority required
Pulmonary arterial hypertension (PAH)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

**Human Services website at www.humanservices.gov.au**

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must not have responded to prior PBS-subsidised therapy with this agent,

AND

The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**EPOPROSTENOL**

**Authority required**

Pulmonary arterial hypertension (PAH)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and

2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
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<td>ECHO composite assessment; and</td>
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<tr>
<td>(iii)</td>
<td>6 Minute Walk Test (6MWT); and</td>
<td></td>
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<tr>
<td>(3)</td>
<td>a signed patient acknowledgement.</td>
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</tbody>
</table>

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note**
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

**Note**
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

**Authority required**
The test results provided must not be more than 2 months old at the time of application. A test conducted must be provided with the authority application.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>Qty $</th>
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</table>

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
- Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three
tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months),
extcept for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability
or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for
assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of
disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement
of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in
the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.
The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5
months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure
continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and
macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue
disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and
PHARMACEUTICAL BENEFACTS THAT HAVE THE FORM EPOPROSTENOL 1.5 MG INJECTION VIAL ARE EQUIVALENT FOR THE PURPOSES OF SUBSTITUTION.

### Pharmaceutical Benefits

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<td>10130E</td>
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</tr>
</tbody>
</table>

**ILOPROST**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the...
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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</table>

following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH; OR
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class IV drug-induced PAH,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
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GPO Box 9826
HOBART TAS 7001
For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restrictions. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

### Clinical criteria:

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

  The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. The results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
4. For WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

### Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
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<td>Note Refer to the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> for a list of designated hospitals.</td>
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<td>Authority required Pulmonary arterial hypertension (PAH)</td>
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<td>Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)</td>
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<td>Clinical criteria:</td>
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<td></td>
<td>Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR</td>
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<td>Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR</td>
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<td>Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND</td>
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<td>The treatment must be the sole PBS-subsidised PAH agent for this condition.</td>
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<td>Applications for authorisation must be in writing and must include:</td>
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<td>(1) a completed authority prescription form; and</td>
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<td>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and</td>
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<td>(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and</td>
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<td>(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.</td>
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<td>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</td>
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<td>The test results provided must not be more than 2 months old at the time of application.</td>
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<td>Response to a PAH agent is defined as follows:</td>
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<td>For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</td>
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<td></td>
<td>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</td>
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<td>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</td>
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<td>For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</td>
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<td>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</td>
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<td>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</td>
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<td>Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.</td>
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<td>Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.</td>
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<td>Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.</td>
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</table>
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who require treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.
MACITENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or heritable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

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GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

i. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
ii. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>HOBART TAS 7001</td>
<td><strong>Note</strong> Refer to the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> for a list of designated hospitals. <strong>Authority required</strong> Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply <strong>Clinical criteria:</strong> Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, <strong>AND</strong> The treatment must be the sole PBS-subsidised PAH agent for this condition, <strong>AND</strong> The treatment must provide no more than the balance of up to six months treatment available under the above restrictions. <strong>Note</strong> Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <strong>Authority required</strong> Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients) <strong>Clinical criteria:</strong> Patient must have received approval for initial PBS-subsidised treatment with this agent, <strong>AND</strong> Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent. <strong>AND</strong> The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only.</td>
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The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
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GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending
order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalfil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Note

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure...
continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

9547L sildenafil 20 mg tablet, 90

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**TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension,
drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Authorised

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)**

**Clinical criteria:**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.
Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
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GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
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**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES
Somatostatin and analogues

LANREOTIDE

Authority required (STREAMLINED)

4570
Acromegaly

Clinical criteria:
The condition must be active,
AND
Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,
AND
The treatment must be after failure of other therapy including dopamine agonists; OR
The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,
AND
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),
AND
The treatment must cease if IGF1 is not lower after 3 months of treatment.
In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

4575
Functional carcinoid tumour

Clinical criteria:
The condition must be causing intractable symptoms,
AND
Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,
AND
Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,
AND
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months’ therapy at a dose of 120 mg every 28 days.
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

5779E
lanreotide 120 mg injection, 1 syringe
2 5 .. $4480.00 Somatuline Autogel IS

5777C
lanreotide 60 mg injection, 1 syringe
2 5 .. $2690.00 Somatuline Autogel IS

5778D
lanreotide 90 mg injection, 1 syringe
2 5 .. $3580.00 Somatuline Autogel IS

LANREOTIDE

Authority required (STREAMLINED)

4567
Acromegaly

Clinical criteria:
The condition must be active,
AND
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**OCTREOTIDE**

**Authority required (STREAMLINED)**

4563

Acromegaly

**Clinical criteria:**

The condition must be controlled with octreotide immediate release injections,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

9511N

octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

2 5 .. *2613.72 Sandostatin LAR NV

9512P

octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

2 5 .. *3479.62 Sandostatin LAR NV

9513Q

octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

2 5 .. *4354.92 Sandostatin LAR NV

**OCTREOTIDE**

**Authority required (STREAMLINED)**
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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| 3407  | Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND:  
(a) after failure of other therapy including dopamine agonists; or  
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or  
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.  
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.  
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily | 18 | 11 | .. | *1236.42 | Hospira Pty Limited HH |
| 3408  | Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.  
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose | 18 | 11 | .. | *619.02 | Hospira Pty Limited HH |

### CALCIUM HOMEOSTASIS

#### ANTI-PARATHYROID AGENTS

##### Other anti-parathyroid agents

**CINACALCET**

**Authority required (STREAMLINED)**

3323  
Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

**Authority required (STREAMLINED)**

3324  
Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

**Note**  
During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.  
During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.  
"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Note**  
Special Pricing Arrangements apply.

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Dispensed Price for Max. Qty
## HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)

### ANTIINFECTIVES FOR SYSTEMIC USE

#### ANTIINFECTIVES FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

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<td>5616N</td>
<td>azithromycin 600 mg tablet, 8</td>
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<td>128.06</td>
<td>Zithromax PF</td>
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**AZITHROMYCIN**

**Authority required (STREAMLINED)**
3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

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<td>5625C</td>
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<td>5624B</td>
<td>clarithromycin 500 mg tablet, 100</td>
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<td>39.93</td>
<td>Klacid GO</td>
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**CLARITHROMYCIN**

**Authority required (STREAMLINED)**
3325
Treatment of Mycobacterium avium complex infections

### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

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<td>5749N</td>
<td>ganciclovir 500 mg injection, 5 x 500 mg vials</td>
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<td>1</td>
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<td>560.00</td>
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**GANCICLOVIR**

**Authority required (STREAMLINED)**
3379
Cytomegalovirus retinitis in severely immunocompromised patients

**Authority required (STREAMLINED)**
3380
Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required (STREAMLINED)**
3381
Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

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<td>9568N</td>
<td>valaciclovir 500 mg tablet, 100</td>
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<td>APO-Valaciclovir TX</td>
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**VALACICLOVIR**

**Authority required (STREAMLINED)**
3419
Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

a Valaciclovir RBX RA
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<td>valganciclovir 450 mg tablet, 60</td>
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<td>*4491.60</td>
<td>Valcyte</td>
<td>RO</td>
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<td>9655E</td>
<td>valganciclovir 50 mg/mL oral liquid: powder for, 100 mL</td>
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<td>*4574.79</td>
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### Phosphonic acid derivatives

**FOSCARNET**

**Authority required (STREAMLINED)**

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<tr>
<td>5747L</td>
<td>FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL</td>
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<td>1177.50</td>
<td>Foscavir</td>
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### Protease inhibitors

**ATAZANAVIR**

**Authority required (STREAMLINED)**

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<td>atazanavir 150 mg capsule, 60</td>
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<td>*1043.82</td>
<td>Reyataz</td>
<td>BQ</td>
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<td>5614L</td>
<td>atazanavir 200 mg capsule, 60</td>
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<td>5</td>
<td>..</td>
<td>*1391.76</td>
<td>Reyataz</td>
<td>BQ</td>
</tr>
<tr>
<td>5612J</td>
<td>atazanavir 300 mg capsule, 30</td>
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<td>5</td>
<td>..</td>
<td>*1043.82</td>
<td>Reyataz</td>
<td>BQ</td>
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**BOCEPREVIR**

**Authority required (STREAMLINED)**

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<td>chronic genotype 1 hepatitis C infection</td>
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</table>
AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

AND

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required (STREAMLINED)

4202

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where
the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and  
(b) 24-hour access by patients to medical advice; and  
(c) an established liver clinic.

---

### Darunavir

**Authority required (STREAMLINED)**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

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<td>Prezista JC</td>
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<tr>
<td>3392M</td>
<td>darunavir 600 mg tablet, 60</td>
<td>2</td>
<td>5</td>
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<td>*2097.42</td>
<td>Prezista JC</td>
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</tbody>
</table>

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### Fosamprenavir

**Authority required (STREAMLINED)**

HIV infection

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
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<tr>
<td><strong>Treatment Phase: Continuing</strong></td>
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<tr>
<td>Clinical criteria:</td>
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<tr>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.</td>
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<td>fosamprenavir 50 mg/mL oral liquid, 225 mL</td>
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<td>5746K</td>
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<td>*758.32</td>
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### INIDINAVIR

**Authority required (STREAMLINED)**

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<td><strong>Treatment Phase: Initial</strong></td>
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<td>Clinical criteria:</td>
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<tr>
<td>Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents.</td>
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<td>5752R</td>
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### RITONAVIR

**Authority required (STREAMLINED)**

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<td><strong>Treatment Phase: Initial</strong></td>
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<td>Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents.</td>
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<td>9542F</td>
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### SAQUINAVIR

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<tr>
<td><strong>Treatment Phase: Continuing</strong></td>
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<tr>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.</td>
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<td>5</td>
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<td>*1011.12</td>
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**Treatment Phase: Initial**

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**Treatment Phase: Continuing**

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

<table>
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</table>

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Authority required (STREAMLINED)**

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<th>No. of Rpts</th>
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</table>

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,
The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

10200W simeprevir sodium 150 mg capsule, 7

6 .. .. "14865.72 Olysio JC

TELAPRE VIR
Authority required (STREAMLINED)

4186

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.
### Authority required (STREAMLINED)

**4191**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- Patient must have compensated liver disease,
  - AND
  - Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
  - AND
  - The treatment must be in combination with peginterferon alfa and ribavirin,
  - AND
  - The treatment must be limited to a maximum duration of 12 weeks,
  - AND
  - The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**
- Patient must be 18 years or older,
  - AND
  - Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
- Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
  - (a) a nurse educator/counsellor for patients; and
  - (b) 24-hour access by patients to medical advice; and
  - (c) an established liver clinic.

### TIPRANAVIR

**Authority required (STREAMLINED)**

**3601**
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note**
- Special Pricing Arrangements apply.

### Nucleoside and nucleotide reverse transcriptase inhibitors

**ABACAVIR**

**Authority required (STREAMLINED)**

**4512**
HIV infection

Treatment Phase: Initial
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<td>Patient must be antiretroviral treatment naive,</td>
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<td>The treatment must be in combination with other antiretroviral agents.</td>
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<tr>
<td></td>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection,</td>
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**ADEFOVIR DIPIVOXIL**

**Authority required (STREAMLINED)**

3973 Chronic hepatitis B in a patient without cirrhosis who has failed antiepadnaviral therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antiepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antiepadnaviral therapy except in patients with evidence of poor compliance

**Authority required (STREAMLINED)**

3974 Chronic hepatitis B in a patient with cirrhosis who has failed antiepadnaviral therapy and who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antiepadnaviral therapy.

5606C adefovir dipivoxil 10 mg tablet, 30 | 2 | 5 | .. | *1050.00 aAPO-Adefovir TX

a Hepsera GI

**DIDANOSINE**

**Authority required (STREAMLINED)**

4512 HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

**AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454 HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

**AND**

The treatment must be in combination with other antiretroviral agents.

5663C didanosine 125 mg capsule: enteric, 30 | 2 | 5 | .. | *280.86 Videx EC BQ

5664D didanosine 200 mg capsule: enteric, 30 | 2 | 5 | .. | *326.80 Videx EC BQ

5665E didanosine 250 mg capsule: enteric, 30 | 2 | 5 | .. | *408.48 Videx EC BQ
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<td>Treatment Phase: Continuing</td>
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<td>Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:</td>
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<td>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or</td>
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<td>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance</td>
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<td>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.</td>
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<td></td>
<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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<td>Note</td>
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<td>PBS-subsidised entecavir monohydrate must be used as monotherapy.</td>
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<td>5712P</td>
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<td><strong>ENTECAVIR</strong></td>
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<td>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;</td>
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<td>(2) Evidence of chronic liver injury as determined by:</td>
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<td>(a) Confirmed elevated serum ALT; or</td>
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<td>(b) Liver biopsy</td>
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<td>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.</td>
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<tr>
<td></td>
<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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<td>Note</td>
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<td>PBS-subsidised entecavir monohydrate must be used as monotherapy.</td>
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<td>5711N</td>
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</table>
### LAMIVUDINE

**Authority required (STREAMLINED)**

- **Code**: 4512
- **Drug**: Lamivudine
- **Indication**: HIV infection
- **Phase**: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

**Dispersed Price for Max. Qty**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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### LAMIVUDINE

**Authority required (STREAMLINED)**

- **Code**: 3961
- **Drug**: Lamivudine
- **Indication**: Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
  1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
  2. Evidence of chronic liver injury as determined by:
     a. Confirmed elevated serum ALT; or
     b. Liver biopsy

**Authority required (STREAMLINED)**

- **Code**: 3962
- **Drug**: Lamivudine
- **Indication**: Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.
- **Clinical criteria:**
  - Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Dispensed Price for Max. Qty**

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### STAVUDINE

**Authority required (STREAMLINED)**

- **Code**: 4512
- **Drug**: Stavudine
- **Indication**: HIV infection
- **Phase**: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive,
### TELBIVUDINE

**Authority required (STREAMLINED)**

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### TENOFOVIR

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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<td>Patient must have previously received PBS-subsidised therapy for HIV infection.</td>
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<td>3970</td>
<td>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.</td>
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<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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</table>

**Patient must not have cirrhosis,**

**AND**

**Patient must be nucleoside analogue naive,**

**AND**

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection.

**AND**

Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy,

**AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

**Note**
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

4476
Chronic hepatitis B

**Clinical criteria:**

Patient must have cirrhosis,

**AND**

Patient must be nucleoside analogue naive,

**AND**

Patient must have detectable HBV DNA,

**AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

4490
Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis,

**AND**

Patient must have failed antihepadnaviral therapy,

**AND**

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Note**
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

4510
Chronic hepatitis B

**Clinical criteria:**

Patient must have cirrhosis,

**AND**

Patient must have failed antihepadnaviral therapy,

**AND**

Patient must have detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antiretroviral therapy.

**ZIDOVUDINE**

**Authority required (STREAMLINED)**

4512

HIV infection

**Treatment Phase: Initial**

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454

HIV infection

**Treatment Phase: Continuing**

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**Non-nucleoside reverse transcriptase inhibitors**

**EFAVIRENZ**

**Authority required (STREAMLINED)**

4512

HIV infection

**Treatment Phase: Initial**

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454

HIV infection

**Treatment Phase: Continuing**

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**ETRAVIRINE**

**Authority required (STREAMLINED)**

3597

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral
experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

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**NEVIRAPINE**

**Authority required (STREAMLINED)**

4512

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**NEVIRAPINE**

**Authority required (STREAMLINED)**

4526

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must have been stabilised on nevirapine immediate release,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**RILPIVIRINE**

**Authority required (STREAMLINED)**

4512

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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### LOPINAVIR + RITONAVIR

**Authority required (STREAMLINED)**

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<td>5790R</td>
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### TENOFOVIR + EMTRICITABINE

**Authority required (STREAMLINED)**

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<td><strong>Clinical criteria:</strong></td>
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</table>
### TENOFOVIR + EMTRICITABINE + Efavirenz

**Authority required (STREAMLINED)**

4522

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

#### Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### TENOFOVIR + EMTRICITABINE + Elvitegravir + Cobicistat

**Authority required (STREAMLINED)**

4522

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

#### Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### Other antivirals

**Dolutegravir**

**Authority required (STREAMLINED)**

4512

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive,

AND

- The treatment must be in combination with other antiretroviral agents.

#### Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

- The treatment must be in combination with other antiretroviral agents.
ENFUVIRIDE
Authority required (STREAMLINED)
3597
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5710M  enfuvirtide 90 mg injection {60 x 90 mg vials} (IS) inert substance diluent {60 x 1.1 mL vials}, 1 pack
   2  5  ..  *4426.00  Fuzeon  RO

MARAVIROC
Authority required (STREAMLINED)
3599
Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5792W  maraviroc 150 mg tablet, 60
   2  5  ..  *1835.40  Celsentri  VI

5793X  maraviroc 300 mg tablet, 60
   2  5  ..  *1835.40  Celsentri  VI

RALTEGRAVIR
Authority required (STREAMLINED)
4275
HIV infection
Treatment Phase: Initial

Clinical criteria:
The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

Population criteria:
Patient must be aged 2 years or older.

Authority required (STREAMLINED)
4274
HIV infection
Treatment Phase: Continuing

Clinical criteria:
The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:
Patient must be aged 2 years or older.

2760G  raltegravir 100 mg tablet: chewable, 60
   6  5  ..  *2025.00  Isentress  MK

2736B  raltegravir 25 mg tablet: chewable, 60
   6  5  ..  *506.28  Isentress  MK
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| 4512  | **RALTEGRAVIR**
Authority required (STREAMLINED)
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive,
AND
The treatment must be in combination with other antiretroviral agents. | 4512 | 2 | 5 | .. *1331.10 | 9523F raltegravir 400 mg tablet, 60 | Isentress | MK |
| 4454  | **RALTEGRAVIR**
Authority required (STREAMLINED)
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection,
AND
The treatment must be in combination with other antiretroviral agents. | 4454 | 2 | 5 | .. *1331.10 | 9523F raltegravir 400 mg tablet, 60 | Isentress | MK |
ANTINEOPLASTIC AGENTS

AZACITIDINE

**Authority required**

Initial PBS-subsidised treatment of a patient with:

1. Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
2. Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a copy of the full blood examination report; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukemia or acute myeloid leukemia; and
(d) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(e) a signed patient acknowledgment form.

No more than three cycles will be authorised

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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| 9598E | Azacitidine 100 mg injection, 1 x 100 mg vial | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised. Note: Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note: Special Pricing Arrangements apply. | 14 | 5 | .. | 7700.00 | Vidaza | CJ |

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

**Anthracyclines and related substances**

DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

**Authority required (STREAMLINED)**

- **3348**
  - Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

**Authority required (STREAMLINED)**

- **3349**
  - Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

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</table>
| 5705G | Doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised. Note: Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note: Special Pricing Arrangements apply. | 4 | 5 | .. | 2093.24 | Caelyx | JC |

**OTHER ANTINEOPLASTIC AGENTS**

**Monoclonal antibodies**

ALEMTUZUMAB

**Authority required (STREAMLINED)**

- **4834**
  - Multiple sclerosis
  - Treatment Phase: Initial
  - Clinical criteria:
    - The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
    - The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
    - The treatment must be as monotherapy, AND
    - Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
    - Patient must be ambulatory (without assistance or support).

  **Treatment criteria:**

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|       |                            | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised. Note: Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note: Special Pricing Arrangements apply. | 14 | 5 | .. | 7700.00 | Vidaza | CJ |

**Liposomal Doxorubicin**

- **ZF**
  - Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

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|       |                            | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
(3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised. Note: Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note: Special Pricing Arrangements apply. | 14 | 5 | .. | 7700.00 | Vidaza | CJ |
Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

**Note**
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note**
Special Pricing Arrangements apply.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium Qty $</th>
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<th>Brand Name and Manufacturer</th>
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<td>10228H</td>
<td>alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial</td>
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<td>*56970.00</td>
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**ALEMTUZUMAB**  
**Authority required (STREAMLINED)**

4829  
Multiple sclerosis  
Treatment Phase: Continuing  

**Clinical criteria:**  
Patient must have previously been issued with an authority prescription for this drug,  

AND  
Patient must not show continuing progression of disability while on treatment with this drug,  

AND  
Patient must not receive more than one PBS-subsidised treatment per year,  

AND  
The treatment must be as monotherapy,  

AND  
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**  
Must be treated by a neurologist.

**Note**
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note**
Special Pricing Arrangements apply.

**Note**
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<td>10232M</td>
<td>alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial</td>
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**IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

**Colony stimulating factors**

**FILGRASTIM**

**Authority required (STREAMLINED)**

3357  
For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required (STREAMLINED)**

3358  
Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Authority required (STREAMLINED)**

3359  
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

**Authority required (STREAMLINED)**
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

**Authority required (STREAMLINED)**

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

**Authority required (STREAMLINED)**

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required (STREAMLINED)**

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required (STREAMLINED)**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required (STREAMLINED)**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required (STREAMLINED)**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required (STREAMLINED)**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required (STREAMLINED)**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required (STREAMLINED)**

3374

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required (STREAMLINED)**

3375

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Authority required (STREAMLINED)**

3376

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required (STREAMLINED)**

3377

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required (STREAMLINED)**

3834

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

- **5829T**
  - filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 853.28
  - Brand Name and Manufacturer: Nivestim HH

- **1123D**
  - filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 2133.18
  - Brand Name and Manufacturer: TevaGrastim AS

- **5742F**
  - filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 2133.18
  - Brand Name and Manufacturer: Neupogen AN

- **9692D**
  - filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 2133.18
  - Brand Name and Manufacturer: Nivestim HH

- **2758E**
  - filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes
  - Max. Qty (Packs): 4
  - No. of Rpts: 11
  - Premium $: 2133.16
  - Brand Name and Manufacturer: Zarzio SZ

- **5741E**
  - filgrastim 300 microgram/mL injection, 10 x 1 mL vials
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 2133.18
  - Brand Name and Manufacturer: Neupogen AN

- **5744H**
  - filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 3419.62
  - Brand Name and Manufacturer: Neupogen AN

- **9694F**
  - filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 3419.62
  - Brand Name and Manufacturer: Nivestim HH

- **2783L**
  - filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes
  - Max. Qty (Packs): 4
  - No. of Rpts: 11
  - Premium $: 3419.60
  - Brand Name and Manufacturer: Zarzio SZ

- **1126G**
  - filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 3419.62
  - Brand Name and Manufacturer: TevaGrastim AS

- **5743G**
  - filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials
  - Max. Qty (Packs): 2
  - No. of Rpts: 11
  - Premium $: 3419.62
  - Brand Name and Manufacturer: Neupogen AN

**LENOGRASTIM**

**Authority required (STREAMLINED)**

3395

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

3396

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

3392

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

**Authority required (STREAMLINED)**

3393

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>Code</th>
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<td>Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin’s lymphoma (intermediate or high grade)</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma</td>
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<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin’s disease</td>
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<td>3405</td>
<td>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma</td>
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<td>LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10</td>
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<td>*1025.00</td>
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<td>*2567.20</td>
<td>Granocyte 34 HH</td>
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PEGFILGRASTIM

Authority required (STREAMLINED)

3357 For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required (STREAMLINED)

3362 A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3363 A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3364 A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3365
### Highly Specialised Drugs Program (Public Hospital)

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<tr>
<td>3369</td>
<td>A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<td>3370</td>
<td>A patient with inoperable Stage III, IVA or IVB squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<td>3371</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia</td>
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<td>3372</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)</td>
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<td>3373</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours</td>
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<tr>
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<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours</td>
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<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma</td>
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<tr>
<td>3376</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease</td>
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<tbody>
<tr>
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<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma</td>
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<tr>
<td>3834</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)</td>
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**Interferons**

**INTERFERON ALFA-2A**

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<th>Dispensed Price for Max. Qty</th>
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<td>Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase</td>
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**Authority required (STREAMLINED)**

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<th>No. of Rpts</th>
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<th>Qty</th>
<th>Dispensed Price for Max. Qty</th>
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<td>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy</td>
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**Authority required (STREAMLINED)**

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<th>Premium $</th>
<th>Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Brand Name and Manufacturer</th>
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| 3962   | Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30...
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<td>*894.00</td>
<td>Roferon-A RO</td>
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<td>*1341.00</td>
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<tr>
<td>5761F</td>
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<td>*1787.40</td>
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<tr>
<td>5762G</td>
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<td>*2681.40</td>
<td>Roferon-A RO</td>
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<td>5768N</td>
<td>interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials</td>
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<td>5763H</td>
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<td>*357.48</td>
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<td>5764J</td>
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<td>*2721.80</td>
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**INTERFERON GAMMA-1B**

**Authority required (STREAMLINED)**

3385

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>5769P</td>
<td>interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials</td>
<td>2</td>
<td>11</td>
<td>..</td>
<td>*2721.80</td>
<td>Imukin BY</td>
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</tbody>
</table>

**PEGINTERFERON ALFA-2A**

**Authority required (STREAMLINED)**

3977

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
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<tr>
<td>3978</td>
<td>Evidence of chronic liver injury as determined by:</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>(a) Confirmed elevated serum ALT; or</td>
<td></td>
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<tr>
<td></td>
<td>(b) Liver biopsy;</td>
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<tr>
<td></td>
<td>(3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B</td>
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</tbody>
</table>

**Authority required (STREAMLINED)**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

**Authority required (STREAMLINED)**

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

1. Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
2. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop

**Caution**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- a nurse educator/counsellor for patients; and
- 24 hour access by patients to medical advice; and
- an established liver clinic; and
- facilities for safe liver biopsy.

**PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Authority required (STREAMLINED)**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir; OR

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with
simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4206
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease,
AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
AND
The treatment must be limited to a maximum duration of 48 weeks,
AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:
Patient must be aged 18 years or older,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4187
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
### Code 9524G
**Name, Restriction, Manner of Administration and Form:** Pegasys RBV

- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Premium $:** *3072.84

**Dispensed Price for Max. Qty $:**

**Brand Name and Manufacturer:** Pegasys RBV

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### Code 9525H
**Name, Restriction, Manner of Administration and Form:** Pegasys RBV

- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Premium $:** *3085.28

**Dispensed Price for Max. Qty $:**

**Brand Name and Manufacturer:** Pegasys RBV

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### Code 9526J
**Name, Restriction, Manner of Administration and Form:** Pegasys RBV

- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Premium $:** *3245.82

**Dispensed Price for Max. Qty $:**

**Brand Name and Manufacturer:** Pegasys RBV

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### Code 9527K
**Name, Restriction, Manner of Administration and Form:** Pegasys RBV

- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Premium $:** *3406.36

**Dispensed Price for Max. Qty $:**

**Brand Name and Manufacturer:** Pegasys RBV

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### Code 1026
**Name, Restriction, Manner of Administration and Form:** Pegasys RBV

- **Max. Qty (Packs):** 2
- **No. of Rpts:** 5
- **Premium $:** *3072.84

**Dispensed Price for Max. Qty $:**

**Brand Name and Manufacturer:** Pegasys RBV

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**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**
### Authority required (STREAMLINED)

**4189**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised treatment for hepatitis C,
- AND
- Patient must have compensated liver disease,
- AND
- Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
- AND
- Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
- AND
- The treatment must be limited to a maximum duration of 48 weeks,
- AND
- The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**
- Patient must weigh at least 27 kg,
- AND
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
- No increase in the maximum quantity or number of units may be authorised.

**Note**
- No increase in the maximum number of repeats may be authorised.

**Note**
- Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
  - (a) a nurse educator/counsellor for patients; and
  - (b) 24-hour access by patients to medical advice; and
  - (c) an established liver clinic.

**Authority required (STREAMLINED)**

**4198**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised treatment for hepatitis C,
- AND
- Patient must have compensated liver disease,
- AND
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,
- AND
- The treatment must be limited to a maximum duration of 48 weeks,
- AND
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

**Population criteria:**
- Patient must weigh at least 27 kg,
- AND
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4199
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease,
AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
AND
The treatment must be limited to a maximum duration of 48 weeks,
AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:
Patient must weigh at least 27 kg,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4192
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12;
The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

4197
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with simprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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PEGINTERFERON ALFA-2B (&) RIBAVIRIN
Authority required (STREAMLINED)

4184
Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4197
Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, and
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C.

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks.
AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

4187

**Chronic non-genotype 1 hepatitis C infection**

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Caution**
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Caution**
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

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<td>peginterferon alfa-2b 80 microgram injection [4 x 80 microgram capsules] (&amp;) ribavirin 200 mg capsule [140 capsules] (&amp;) inert substance diluent [4 x 0.5 mL capsules], 1 pack</td>
<td>2</td>
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<td>*2707.66</td>
<td>Pegatron MK</td>
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</tbody>
</table>

**Other immunostimulants**

**PLERIXAFOR**

**Authority required (STREAMLINED)**

4549
Mobilisation of haematopoietic stem cells

**Clinical criteria:**
The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF),

AND
Patient must have lymphoma; OR
Patient must have multiple myeloma,

AND
Patient must require autologous stem cell transplantation,

AND
Patient must have failed previous stem cell collection; OR
Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

**Note**
Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>10083Q</td>
<td>plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial</td>
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<td>..</td>
<td>6991.00</td>
<td>Mozobil GZ</td>
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</tbody>
</table>
IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDS) which must include at least 3 months continuous treatment with each of at least 2 DMARDS, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDS which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDS: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDS which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDS, with one or more of the following DMARDS being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDS trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDS for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDS.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDS cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDS specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- Either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one i.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

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### Highly Specialised Drugs Program (Public Hospital) | Code | Name | Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium Price for Max. Qty $ | Dispensed Qty $ | Brand Name and Manufacturer
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**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium Price for Max. Qty $ | Dispensed Qty $ | Brand Name and Manufacturer |
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

**Rituximab patients:**
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

**(2) Swapping therapy.**
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

**Abatacept patients:**
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**(3) Baseline measurements to determine response**

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis.

**AND**
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy.

**AND**
Patient must not receive more than 16 weeks of treatment under this restriction.

**AND**
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.
Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- A patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify.
with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment.

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis,
- Patient must have demonstrated an adequate response to treatment with this drug,
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- and either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010, contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one i.v. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the i.v. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
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<th>No. of Rpts</th>
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**ECULIZUMAB**

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – New patient

**Clinical criteria:**

- Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition,
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition,
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:
   - An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   - An eGFR within +/- 25% from baseline; or
   - An avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.
The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – beyond initial 48 weeks of treatment

Clinical criteria:

Patient must have received 48 weeks of treatment under Initial treatment-New patient, Initial treatment-Balance of supply and Continuing treatment-New patient with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition,

AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min),

AND
Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:

   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

   b) An eGFR within +/- 25% from baseline; or

   c) An avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

**PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.** A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

1. A completed authority prescription form; and

2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

3. A copy of a current Certificate of vaccination; and

4. A measurement of body weight at the time of application; and

5. A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

6. Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

7. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

8. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note**

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**

**WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current...
medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recomencement of treatment after an initial 48-week period

**Clinical criteria:**

Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition, AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.
The authority application must be in writing and must include:

1. A completed authority prescription form(s); and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2- Recommencement of treatment after an initial 48-week period; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of a current Certificate of vaccination; and
5. A measurement of body weight at the time of application, and
6. A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
7. Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
8. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
9. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

Clinical criteria:

Patient must have received Initial treatment 2-recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition,
Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition.

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:

   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

   b) an eGFR within +/- 25% from baseline; or

   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

1. A completed authority prescription form; and

2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

3. A copy of a current Certificate of vaccination; and

4. A measurement of body weight at the time of application; and

5. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

6. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

7. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note**

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial 3 - Grandfather eculizumab patients

**Clinical criteria:**

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS,

AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014,

AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application,

AND

Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response,

AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition,

AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L ; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or

(iv) a renal biopsy


A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab;
   b) an eGFR within +/- 25% from baseline;
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented;
2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of a current Certificate of vaccination; and
5. A measurement of body weight at the time of application; and
6. The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and
7. Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and
8. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and
9. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis; unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
10. A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and
11. Where available in the week prior to commencing eculizumab results demonstrating:
   a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
      i) presence of schistocytes on blood film;
      ii) low or absent haptoglobin;
      iii) lactate dehydrogenase (LDH) above normal range;
   OR
   b) tissue biopsy confirming TMA in patients who don't have evidence of platelet consumption and haemolysis; AND
   c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
      a) kidney impairment as demonstrated by one of the following:
         i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

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(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab;
   b) an eGFR within +/- 25% from baseline;
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented;
2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of a current Certificate of vaccination; and
5. A measurement of body weight at the time of application; and
6. The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and
7. Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and
8. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and
9. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis; unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
10. A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and
11. Where available in the week prior to commencing eculizumab results demonstrating:
   a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
      i) presence of schistocytes on blood film;
      ii) low or absent haptoglobin;
      iii) lactate dehydrogenase (LDH) above normal range;
   OR
   b) tissue biopsy confirming TMA in patients who don't have evidence of platelet consumption and haemolysis; AND
   c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
      a) kidney impairment as demonstrated by one of the following:
         i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

**Note**

**WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

- Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use.

- Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**ECULIZUMAB**

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient – Balance of Supply

**Clinical criteria:**

Patient must have received PBS-subsidised initial supply of eculizumab for this condition,

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample,

AND

Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

**Note**
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

**Note**

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

**Note**

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

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**ECULIZUMAB**

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient

**Clinical criteria:**

Patient must have active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L;

AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days,

AND

Patient must have clinical features of active organ damage or impairment,

AND

Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

1. a platelet count of less than 150x10^9/L; and evidence of two of the following:
   1. presence of schistocytes on blood film;
   2. low or absent haptoglobin;
   3. lactate dehydrogenase (LDH) above normal range;
   OR
   2. tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

   AND

   3. evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
   (a) kidney impairment as demonstrated by one of the following:
   1. a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
   2. a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   3. a sCr of greater than the age-appropriate ULN in paediatric patients; or
   (iv) a renal biopsy
(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment

The authority application must be in writing and must include:

(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form- Initial PBS-subsidised eculizumab treatment; and
(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) A copy of a current Certificate of vaccination; and
(5) A measurement of body weight at the time of application; and
(6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
(7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment 1-balance of supply; and
(8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
(9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
(10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).

Note
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note
WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.
### Everolimus

**Authority required (STREAMLINED)**  
3355  
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**  
3356  
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**  
Careful monitoring of patients is mandatory.

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### Mycophenolate

**Authority required (STREAMLINED)**  
4084  
Prophylaxis of renal allograft rejection  
Treatment Phase: Management

**Clinical criteria:**  
The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**  
4095  
WHO Class III, IV or V lupus nephritis  
Treatment Phase: Management

**Clinical criteria:**  
The condition must be proven by biopsy.

**Treatment criteria:**  
Must be treated by a nephrologist or in consultation with a nephrologist.  
The name of the consulting nephrologist must be included in the patient medical records.

**Caution**  
Careful monitoring of patients is mandatory.

**Note**  
Management includes initiation, stabilisation and review of therapy as required.

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**Note**  
For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**MYCOPHENOLATE**

**Authority required (STREAMLINED)**

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

3356

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**

Careful monitoring of patients is mandatory.

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<td>Mycophenolate Sandoz SZ</td>
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<td></td>
<td>Pharmacor CR</td>
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<td>Mycophenolate 500</td>
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</tbody>
</table>

**NATALIZUMAB**

**Authority required (STREAMLINED)**

3425

Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the patient’s medical notes, unless written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient is included in the patient’s medical notes.

Natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab

**Caution**

Progressive multifocal leukoencephalopathy has been reported with this drug.

**Note**

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Note**

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9505G</td>
<td>natalizumab 300 mg/15 mL injection, 1 x 15 mL vial</td>
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<td>5</td>
<td>..</td>
<td>1568.04</td>
<td>Tysabri BD</td>
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</table>

**SIROLIMUS**

**Authority required (STREAMLINED)**

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**

Careful monitoring of patients is mandatory.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9549N</td>
<td>sirolimus 1 mg tablet, 100</td>
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<td>5</td>
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<td>Rapamune PF</td>
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<tr>
<td>9550P</td>
<td>sirolimus 1 mg/mL oral liquid, 60 mL</td>
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<td>*936.00</td>
<td>Rapamune PF</td>
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<td>5</td>
<td>..</td>
<td>*2893.34</td>
<td>Rapamune PF</td>
</tr>
<tr>
<td>9747B</td>
<td>sirolimus 500 microgram tablet, 100</td>
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<td>5</td>
<td>..</td>
<td>*723.34</td>
<td>Rapamune PF</td>
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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td><strong>Tumor necrosis factor alpha (TNF-) inhibitors</strong></td>
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<td></td>
<td><strong>ADALIMUMAB</strong></td>
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<td><strong>Authority required</strong></td>
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<tr>
<td></td>
<td>Severe active juvenile idiopathic arthritis</td>
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<td></td>
<td><strong>Clinical criteria:</strong></td>
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<tr>
<td></td>
<td>Patient must have severe active juvenile idiopathic arthritis, AND</td>
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<td></td>
<td>Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR</td>
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<td></td>
<td>Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND</td>
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<td></td>
<td>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR</td>
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<td></td>
<td>Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND</td>
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<td></td>
<td>Patient must not receive more than 16 weeks of treatment under this restriction.</td>
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<td><strong>Population criteria:</strong></td>
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<td></td>
<td>Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.</td>
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<td><strong>Treatment criteria:</strong></td>
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<td>Must be treated by a paediatric rheumatologist; OR</td>
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<td></td>
<td>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</td>
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<td>For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.</td>
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<td></td>
<td>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</td>
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<td>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</td>
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<td>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</td>
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<td>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</td>
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</table>

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be under 18 years of age.

Treatment criteria:
Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.
Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.
If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [Further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is...
Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment;

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2)
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may try an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9661L</td>
<td>adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes</td>
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<td>..</td>
<td>1630.00</td>
<td>Humira</td>
</tr>
<tr>
<td>9663N</td>
<td>adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges</td>
<td>1</td>
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<td>..</td>
<td>1630.00</td>
<td>Humira</td>
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<tr>
<td>9662M</td>
<td>adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>1630.00</td>
<td>Humira</td>
</tr>
</tbody>
</table>

**ETANERCEPT**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
Patient must have received prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 [change or recommencement of treatment after break of less than 12 months]

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

**AND**

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

**AND**
Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab,
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, or on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**
Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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### INFLIXIMAB

**Authority required (STREAMLINED)**

Acute severe ulcerative colitis

**Clinical criteria:**

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application,

AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below,

AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide...
Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**Note**
No increase in the maximum number of repeats may be authorised.

10067W infliximab 100 mg injection, 1 x 100 mg vial 5 1 * 3758.50 Remicade JC

**INFLIXIMAB**

**Authority required**
Moderate to severe ulcerative colitis

**Treatment Phase: Initial treatment (new patient)**

**Clinical criteria:**
Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal,

AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal,

AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**
Patient must be 6 years of age or older.

**Treatment criteria:**
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient’s condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or PUCAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and
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acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note**
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
Special Pricing Arrangements apply.

**Authority required**
Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)

**Clinical criteria:**
Patient must have been receiving treatment with this drug prior to 1 December 2014, AND

Patient must have had a Mayo clinic score greater than or equal to 6 at the time of application.

Patient must have had a partial Mayo clinic score greater than or equal to 6 provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**
Patient must be 6 years of age or older.

**Treatment criteria:**
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient’s condition and

(ii) the date of commencement of this drug and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.
Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note**
Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
GPO Box 9826
HOBART TAS 7001

**Note**
Special Pricing Arrangements apply.

**Authority required**
Moderate to severe ulcerative colitis

**Treatment Phase: Balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients).

**Population criteria:**
- Patient must be 6 years of age or older.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

**Note**
Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
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<td>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. <strong>Note</strong> Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs GPO Box 9826 HOBART TAS 7001 <strong>Note</strong> Special Pricing Arrangements apply. <strong>Authority required</strong> Moderate to severe ulcerative colitis <strong>Treatment Phase: Balance of supply</strong> <strong>Clinical criteria:</strong> Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients). <strong>Population criteria:</strong> Patient must be 6 years of age or older. <strong>Treatment criteria:</strong> Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years. <strong>Note</strong> Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826</td>
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| HOBART TAS 7001 | Note
| Special Pricing Arrangements apply. | Authority required
| Moderate to severe ulcerative colitis | Treatment Phase: Continuing treatment |
| Clinical criteria: | Patient must have previously been issued with an authority prescription for this drug for this condition, AND |
| Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR |
| Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years. |
| Treatment criteria: | Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR |
| Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years. |
| Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. |
| Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. |
| At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. |
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| Note
Special Pricing Arrangements apply. |

10196P infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 751.70 Remicade JC

### INFliximab

**Authority required**
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASM); or (iii) limitation of chest expansion relative to...
normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must be assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a new course of treatment within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

AND

complete 18 weeks treatment,

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment, OR

Patient must have received insufficient therapy with this drug under the initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Ankylosing spondylitis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must completing their current course of treatment and that an application is posted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised bDMARD therapy with that agent (Initial 2).

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

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**Note**

**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised bDMARD therapy with that agent (Initial 2).

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

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The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis, 

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, 

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**INFLIXIMAB**

**Authority required**

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians (internal medicine specialising in gastroenterology (code 81)) or consultant physicians (general medicine specialising in gastroenterology (code 82)).
If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient’s condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient’s condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of...
infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or...
consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:
   (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
   (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
   (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
   AND/OR
   (b) be assessed clinically as being in a high faecal output state;
   AND/OR
   (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]] which includes the following:
   (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
   (iii) date of the most recent clinical assessment; and
   (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

**NOTE:** Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.
The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course demonstrated.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii) details of prior TNF alpha antagonist treatment including details of dose and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.
to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult the relevant TGA-approved Product Information.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy); and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient’s condition, if relevant; and

(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 3 (grandfather)
The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response consultant physicians [general medicine specialising in gastroenterology (code 82)].

Those patients who meet the continuation criterion, and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course immediately prior to commencing treatment with infliximab.

(b) improvement of intestinal inflammation as demonstrated by:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

**Initial 3**

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the NOTE below,

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patents may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the

**TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE**

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A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time
Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

INFLIXIMAB

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient’s condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of
Continuing PBS-subsidised treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) as compared to baseline AND a total PCDAI score of 30 points or less.

Authorities required
Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authorities required
Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab or fail to meet the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

5755X  infliximab 100 mg injection, 1 x 100 mg vial  1  ..  ..  751.70  Remicade  JC

INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:
Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note**

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note**

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis.

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 3).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment,

**AND**
The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis,

**AND**
Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

**AND**
Patient must demonstrate, at the time of application, an adequate response to treatment with this drug.

**AND**
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthropathies are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a
particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have not previously received PBS-subsidised treatment with that particular biological agent; or

(ii) patients have received prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(iii) patients have received no prior PBS-subsidised biological treatment with that particular biological agent previously; or

(iv) patients have received prior PBS-subsidised biological treatment with that particular biological agent previously, and do not wish to continue such treatment (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(v) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not previously received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>Code</th>
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<td>(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.</td>
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Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis

**Treatment Phase: Continuing treatment - balance of supply**

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

5756Y

infliximab 100 mg injection, 1 x 100 mg vial

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**INFlixIMAB**

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)**

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 22 weeks of treatment under this restriction,
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

Special Pricing Arrangements apply.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterupted bDMARD.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with the specific bDMARD. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Rituximab patients:

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that drug.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with the specific bDMARD. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements for the patient's response to treatment at each course of PBS-subsidised therapy.
At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
(a) a completed authority prescription form; and
The authority application must be made in writing and must include:
tocilizumab.
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
AND either of the following:
Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the
population criteria:
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are
eligible to receive further bDMARD therapy,
AND
Patient must not receive more than 22 weeks of treatment under this restriction,
AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or
tocilizumab.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the
weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.
Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must
be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised infliximab treatment, within the timeframes
specified below.
Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the
patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4
weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have
been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to
treatment with infliximab.
If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised
treatment with this drug for this condition.
A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least
22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND
OR
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>Due to active disease and not irreversible damage as joint destruction or bony overgrowth.</td>
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Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note
Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) - balance of supply.

Clinical criteria:

Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment,

AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with infliximab,

AND

Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. Restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with...
### Highly Specialised Drugs Program (Public Hospital)

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed to respond to treatment with that bDMARD.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**

Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

| Code   | Name, Restriction, Manner of Administration and Form Max. Qty No. of Rpts Premium $ Qty Price for Max. $ Brand Name and Manufacturer |
|--------|-------------------------------------------------|-----------------|----------|----------------|-----------------|-----------------|---------------|
| 5757B  | infliximab 100 mg injection, 1 x 100 mg vial    | 1               | ..       | ..             | 751.70          | Remicade        | JC            |

**INFLIXIMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each recent prior treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment will be provided. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatement as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,
to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, may commence a further course of treatment within that Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under (4) ‘Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a
patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

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INFLIXIMAB
Authority required
Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.
The most recent fistula assessment must be no more than 1 month old at the time of application.

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

[www.medicareaustralia.gov.au] which includes the following:

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab or up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised infliximab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

**Initial 3 (grandfather)**

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not
meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised TNF-alfa antagonist treatment. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month they respond to treatment with that TNF-alfa antagonist.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed the treatment.

(iii) A patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent; or

Further details are under ‘Swapping therapy’ below.

Initial treatment authorisations will be limited to provide for a maximum of 14 weeks of therapy for adalimumab and 16 weeks of therapy for infliximab.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be written for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in this publication, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alterate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

### Interleukin inhibitors

**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

**AND**

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

**AND**

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.
AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD therapy.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested.
Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.
Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).  

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.  

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.  

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.  

(b) Continuing treatment.  

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.  

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.  

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.  

(2) Swapping therapy.  

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.  

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.  

(3) Baseline measurements to determine response.  

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.  

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.  

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.  

(5) Withdrawal of treatment after sustained remission.  

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.  

**Authority required**  
Severe active juvenile idiopathic arthritis  
Treatment Phase: Continuing Treatment – balance of supply  

**Clinical criteria:**  
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND  
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.  

**Treatment criteria:**  
Must be treated by a rheumatologist; OR
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Note**

- Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
  - Department of Human Services
  - Prior Written Approval of Complex Drugs
  - Reply Paid 9826
  - GPO Box 9826
  - HOBART TAS 7001

**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,
- **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; **OR**
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,
- **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which include at least 3 months continuous treatment with each of at least 2 DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,
- **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDS trialled, their doses and duration of treatment, and all relevant contraindications and/or...
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised bDMARD therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from...
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD, provided they have demonstrated an adequate response to treatment. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

A patient may swap to an alternate bDMARD without having to requalify for treatment under the Initial 2 treatment restriction provided they have demonstrated an adequate response to treatment. A patient who wishes to re-commence a treatment cycle following a break in PBS-subsidised bDMARD therapy of more than 24 months (Initial 1); or a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or a patient wishes to re-commence therapy with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
### Authority Approval for Sufficient Therapy

- **Severe active juvenile idiopathic arthritis**
- **Treatment Phase:** Continuing treatment

#### Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

  **AND**
  - Patient must have demonstrated an adequate response to treatment with tocilizumab,

  **AND**
  - Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

  **AND**
  - Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### Population criteria:
- Patient must be aged 18 years or older.

#### Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.
All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and the length of a treatment break is measured from the date the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

10058J tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial 1 . . . 467.20 Actemra RO
TOCILIZUMAB

Authority required

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

—— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or

(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR

(c) has refractory systemic symptoms, demonstrated by:

—— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND

(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

(a) in a patient with polyarticular course disease:

(i) an active joint count of at least 20 active (swollen and tender) joints; OR

(ii) at least 4 active joints from the following list:

—— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR

—— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) an active joint count of at least 2 active joints; AND

(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR

(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.
At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Authority required**

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Authority required**

Initial 3 (‘grandfather’ patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(ii) pathology reports detailing CRP.
The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month’s supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month’s supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the...
month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD tried.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing
TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of...
treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

Note

Special Pricing Arrangements apply.

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**TOCILIZUMAB**

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)**

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis,

**AND**

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

**AND**

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

**AND**

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

**AND**

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.
**TREATMENT CRITERIA:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth);

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

Special Pricing Arrangements apply.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of...
Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

**Applications for initial treatment should be made where:**

(i) a patient has received prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD agent.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that drug providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,
AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy.

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and
Initial applications for new or re-commencing bDMARD treatment may be submitted to the Department of Human Services on 1800 700 270. Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

Restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment.

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the
Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment.

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis,
AND
Patient must have demonstrated an adequate response to treatment with tocilizumab,
AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,
AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be aged 18 years or older.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has failed to respond to treatment with that bDMARD.

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two
It is recommended that a patient be reviewed in the mon-
requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Abatacept patients:
- Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Rituximab patients:
- A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Abatacept patients:
- Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab patients:
- A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

(2) Swapping therapy.

Rituximab patients:
- A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority application.

Rituximab patients:
- A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Abatacept patients:
- Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total number of major joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
- Severe active rheumatoid arthritis
- Treatment Phase: Continuing Treatment – balance of supply.
Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Calcineurin inhibitors

CYCLOSPORIN

Authority required (STREAMLINED)
3328
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

Authority required (STREAMLINED)
3329
Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required (STREAMLINED)
3330
Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

Authority required (STREAMLINED)
3331
Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

Authority required (STREAMLINED)
3332
Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

Caution
Careful monitoring of patients is mandatory.

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**Other immunosuppressants**

LENALIDOMIDE

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

The treatment must be limited to a maximum duration of 16 weeks,

**AND**

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

**AND**

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

**AND**

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (other abnormalities), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.
Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and

would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome,

AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide,

AND

Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Prior Written Approval of Complex Drugs**

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

Special Pricing Arrangements apply.

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**LENALIDOMIDE**

**Authority required**

Multiple myeloma

**Treatment Phase:** Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis,
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone,
- Patient must have progressive disease after at least one prior therapy,
- Patient must have undergone or be ineligible for a primary stem cell transplant,
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:
Patient must have previously received an authority prescription for lenalidomide,

AND
Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR
The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.**

**Note**

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

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### RITUXIMAB

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis,
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,
- Patient must not have not failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,
- Patient must not receive more than 2 infusions of rituximab under this restriction,
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the tocilizumab

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there

(3) a signed patient acknowledgement.

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(1) completed authority prescription form(s); and

The application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
Note
Special Pricing Arrangements apply.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

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Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 6 months may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
- a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients
must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis,

AND
Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND
Patient must not receive more than 2 infusions of rituximab under this restriction,

AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab

The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Special Pricing Arrangements apply.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of treatment with a PBS-subsidised TNF-alpha antagonist.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uniformity in dose prescription and to provide an opportunity to assess response to treatment. Continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive a further course of treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD treatment.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencement treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Rituximab patients:

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<tr>
<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium Qty $</th>
<th>Brand Name and Manufacturer</th>
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**THALIDOMIDE**

**Authority required (STREAMLINED)**

3342
Multiple myeloma

**Caution**
Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note**
Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

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## MUSCULO-SKELETAL SYSTEM

### MUSCLE RELAXANTS

#### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

**Other centrally acting agents**

**BACLOFEN**

**Authority required (STREAMLINED)**

- **3318**
  Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

- **Authority required (STREAMLINED)**
  **3319**
  Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

- **Authority required (STREAMLINED)**
  **3320**
  Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

- **Authority required (STREAMLINED)**
  **3321**
  Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

**5617P**

- Baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule
- 10
- ...
- ...
- *1483.70
- Lioresal Intrathecal
- NV

### DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

**IBANDRONIC ACID**

**Authority required (STREAMLINED)**

- **3343**
  Bone metastases from breast cancer

**5750P**

- Ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial
- 1
- 11
- ...
- 341.36
- Bondronat
- RO

**PAMIDRONATE DISODIUM**

**Authority required (STREAMLINED)**

- **4433**
  Hypercalcaemia of malignancy

  **Clinical criteria:**
  Patient must have a malignancy refractory to anti-neoplastic therapy.

**5667G**

- Pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial
- 4
- 2
- ...
- *68.64
- Pamisol
- HH

**5669J**

- Pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial
- 1
- 2
- ...
- 68.65
- Pamisol
- HH

**PAMIDRONATE DISODIUM**

**Authority required (STREAMLINED)**

- **4425**
  Hypercalcaemia of malignancy

  **Clinical criteria:**
  Patient must have a malignancy refractory to anti-neoplastic therapy.

  **Note**
  Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

**5702D**

- Pamidronate disodium 30 mg injection [2 x 30 mg
- 1
- 2
- ...
- 68.66
- \(^a\) Aredia 30 mg
- NV
## PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

- **4421**
  - Hypercalcaemia of malignancy
  
  **Clinical criteria:**
  
  Patient must have a malignancy refractory to anti-neoplastic therapy.

## ZOLEDRONIC ACID

**Authority required (STREAMLINED)**

- **3342**
  - Multiple myeloma

## Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.

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## NERVOUS SYSTEM

### ANTI-PARKINSON DRUGS

#### DOPAMINERGIC AGENTS

**Dopa and dopa derivatives**

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required (STREAMLINED) 3704**

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

**Note**

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

**9743T**

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<th>Levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags</th>
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**Dopamine agonists**

**APOMORPHINE**

**Authority required (STREAMLINED) 4833**

Parkinson disease

**Clinical criteria:**

Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**10227G**

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**5609F**

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### PSYCHOLEPTICS

#### ANTIPSYCHOTICS

**Diazepines, oxazepines, thiazepines and oxepines**

**CLOZAPINE**

**Authority required (STREAMLINED) 4411**

Schizophrenia

**Clinical criteria:**

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month’s supply. Up to 5 repeats will be authorised.

**Note**

Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (CPMPlus) or Clopineconnect.

**5629G**

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RESPIRATORY SYSTEM

**DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

### Other systemic drugs for obstructive airway diseases

**OMALIZUMAB**

**Authority required**

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

- (a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
  - (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
  - (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
  - (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and
- (b) duration of asthma of at least 1 year; and
- (c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and
- (d) past or current evidence of atopy, documented by skin prick testing or RAST; and
- (e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and
- (f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
  - (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
  - (ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
  - (iii) the signed patient acknowledgement; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the ACQ-5 calculation sheet).
Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a documented history of severe allergic asthma; and

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician
This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The assessment of the patient’s continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient’s continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing (b) Continuing treatment.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ-5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire [ACQ-5] score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients ‘grandfathered’ onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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<th>Code</th>
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'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note**

Special Pricing Arrangements apply.

**COUGH AND COLD PREPARATIONS**

**EXpectorants, excl. combinations with Cough Suppressants**

**Mucolytics**

**DORNASE ALFA**

**Authority required (STREAMLINED)**

4288

Cystic fibrosis

**Clinical criteria:**

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight.

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND

(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)
### Authority required (STREAMLINED)

**Code:** 4300  
**Name:** Cystic fibrosis

**Clinical criteria:**
- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**
- Patient must be less than 5 years of age.
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

### Authority required (STREAMLINED)

**Code:** 4296  
**Name:** Cystic fibrosis

**Clinical criteria:**
- Patient must have initiated treatment with dornase alfa at an age of less than 5 years,  
  AND
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**
- Patient must be 5 years of age or older.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

### Authority required (STREAMLINED)

**Code:** 4298  
**Name:** Cystic fibrosis

**Clinical criteria:**
- Patient must have initiated treatment with dornase alfa prior to 1 November 2009,  
  AND
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**
- Patient must be less than 5 years of age.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**
- Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note**
- It is highly desirable that all patients be included in the national cystic fibrosis patient database.

### Dispensed Price for Max. Qty

**Code:** 5704F  
**Brand Name and Manufacturer:** Pulmozyme

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HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

**Clinical criteria:**
Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol.

**AND**
Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height.

**AND**
Patient must be intolerant or inadequately responsive to dornase alfa.

**AND**
Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**
Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:
(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND
(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

**Authority required (STREAMLINED)**
4293
Cystic fibrosis

**Clinical criteria:**
Patient must have initiated treatment with mannitol prior to 1 August 2012.

**AND**
Patient must have undergone a comprehensive assessment involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

**Population criteria:**
Patient must be 6 years of age or older.

Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**
Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note**
It is highly desirable that all patients be included in the national cystic fibrosis patient database.
OTHER RESPIRATORY SYSTEM PRODUCTS

IVACAFTOR

Authority required
Cystic fibrosis

Treatment Phase: Initial treatment – New patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, liraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
(5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and
(7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(8) a copy of a sweat chloride result; and
(9) height and weight measurements at the time of application; and
(10) a baseline measurement of the number of days of hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required
Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month’s supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, liraconazole, ketoconazole, lopinavir/ritonavir, mibebradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1) a completed authority prescription form; and

2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

5) a recent sweat chloride result; and

6) height and weight measurements at the time of application; and

7) a measurement of number of days of hospitalisation (including hospital in the home) in the previous 6 months.

Authority required

Cystic fibrosis

Treatment Phase: initial treatment - Grandfather patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014,

AND

Patient must have received treatment with ivacaftor within the last 6 months at the time of application,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,
Population criteria:

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, neflinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcilin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and
(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and
(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and
(11) height and weight measurements at the time of application; and
(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and
(13) a baseline measurement of number of days of hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
(14) a measurement of the number of days of hospitalisation (including hospital-in-the home) in the 6 months prior to the date of application; and
(15) dates of prior ivacaftor therapy.

Note
Special Pricing Arrangements apply.

Note
No increase in the maximum number of repeats may be authorised.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10170G</td>
<td>ivacaftor 150 mg tablet, 56</td>
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<td>22500.00</td>
<td>Kalydeco</td>
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## VARIOUS

### ALL OTHER THERAPEUTIC PRODUCTS

**Iron chelating agents**

**DEFERASIROX**  
*Authority required (STREAMLINED)*  
3828  
Chronic iron overload in patients with disorders of erythropoiesis

**Note**  
Special Pricing Arrangements apply.

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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5654N</td>
<td>deferasirox 125 mg tablet: dispersible, 28</td>
<td>6</td>
<td>5</td>
<td>..</td>
<td>*1401.48</td>
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<td>5655P</td>
<td>deferasirox 250 mg tablet: dispersible, 28</td>
<td>6</td>
<td>5</td>
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<td>5656Q</td>
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**DEFERIPRONE**  
*Authority required (STREAMLINED)*  
3338  
Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

**Note**  
Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

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<tr>
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<tr>
<td>5658T</td>
<td>deferiprone 100 mg/mL oral liquid, 250 mL</td>
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<td>..</td>
<td>*1126.40</td>
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<td>deferiprone 500 mg tablet, 100</td>
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<td>Ferriprox</td>
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**DESFERROXAMINE**  
*Authority required (STREAMLINED)*  
3340  
Disorders of erythropoiesis associated with treatment-related chronic iron overload

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<tr>
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<tr>
<td>5661Y</td>
<td>desferrioxamine mesylate 2 g injection, 1 x 2 g vial</td>
<td>60</td>
<td>5</td>
<td>..</td>
<td>*1724.40</td>
<td>a Hospira Pty Limited HH</td>
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<tr>
<td>5662B</td>
<td>desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials</td>
<td>40</td>
<td>5</td>
<td>..</td>
<td>*2874.40</td>
<td>a Hospira Pty Limited HH</td>
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</table>

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

**LANTHANUM**  
*Authority required (STREAMLINED)*  
4832  
Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**  
The condition must not be adequately controlled by calcium,  
AND  
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR  
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,  
AND  
The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**  
Patient must be undergoing dialysis for chronic kidney disease.

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<tr>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>5782H</td>
<td>LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90</td>
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<td>*890.02</td>
<td>Fosrenol</td>
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<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
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<td>No. of Rpts</td>
<td>Premium</td>
<td>Dispensed Price for Max. Qty $</td>
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<tr>
<td>5780F</td>
<td>LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90</td>
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<td>5</td>
<td>..</td>
<td>*523.54</td>
<td>Fosrenol ZI</td>
</tr>
<tr>
<td>5781G</td>
<td>LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*790.56</td>
<td>Fosrenol ZI</td>
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</tbody>
</table>

**SEVELAMER**  
*Authority required (STREAMLINED)*  
4832  
Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation  

**Clinical criteria:**  
The condition must not be adequately controlled by calcium,  
AND  
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR  
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,  
AND  
The treatment must not be used in combination with any other phosphate binding agents.  

**Treatment criteria:**  
Patient must be undergoing dialysis for chronic kidney disease.  

<table>
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<tr>
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<th>Premium</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9546K</td>
<td>sevelamer hydrochloride 800 mg tablet, 180</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*620.00</td>
<td>Renagel GZ</td>
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</tbody>
</table>

**SUCROFERRIC OXYHYDROXIDE**  
*Authority required (STREAMLINED)*  
4832  
Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation  

**Clinical criteria:**  
The condition must not be adequately controlled by calcium,  
AND  
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR  
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,  
AND  
The treatment must not be used in combination with any other phosphate binding agents.  

**Treatment criteria:**  
Patient must be undergoing dialysis for chronic kidney disease.  

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<th>Premium</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10233N</td>
<td>iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90</td>
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<td>*753.46</td>
<td>Velphoro FN</td>
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</table>
SECTION 100 (BOTULINUM TOXIN PROGRAM)

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
</table>

**BOTULINUM TOXIN TYPE A**

**Criteria for availability**

Blepharospasm or hemifacial spasm

**Population criteria:**

Patient must be aged 12 years or older.

**Note**

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**

Dynamic equinus foot deformity

**Clinical criteria:**

The condition must be due to spasticity,

AND

Patient must be an ambulant cerebral palsy patient.

**Population criteria:**

Patient must be aged from 2 to 17 years inclusive.

**Note**

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**

Dynamic equinus foot deformity

**Clinical criteria:**

The condition must be due to spasticity,

AND

Patient must be an ambulant cerebral palsy patient,

AND

Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.

**Population criteria:**

Patient must be aged 18 years or older.

**Note**

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**

Spasmodic torticollis

**Clinical criteria:**

The treatment must be as monotherapy; OR

The treatment must be as adjunctive therapy to current standard care.

**Note**

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

Patient must have cerebral palsy.

**Population criteria:**

Patient must be aged from 2 to 17 years inclusive.

**Note**
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</table>

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Moderate to severe spasticity of the upper limb

**Clinical criteria:**
- Patient must have cerebral palsy,
- AND
- Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.

**Population criteria:**
- Patient must be aged 18 years or older.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
- The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
- Patient must be an adult.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Severe primary axillary hyperhidrosis

**Clinical criteria:**
- Patient must have previously failed or be intolerant to topical aluminium chloride hexahydrate after one to two months of treatment.

**Population criteria:**
- Patient must be aged 12 years or older.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Urinary incontinence

**Clinical criteria:**
- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study,
The condition must be inadequately controlled by anti-cholinergic therapy,

AND

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,

AND

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,

AND

Patient must be willing and able to self-catheterise.

Population criteria:

Patient must have multiple sclerosis; OR

Patient must have a spinal cord injury; OR

Patient must be aged 18 years or older and have spina bifida.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note

Special Pricing Arrangements apply.

Criteria for availability

Chronic migraine

Clinical criteria:

Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin,

AND

Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin,

AND

Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment.

Population criteria:

Patient must be an adult.

Medication overuse headache must be appropriately managed prior to initiation of treatment with botulinum toxin.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note

Special Pricing Arrangements apply.

Criteria for availability

Urinary incontinence

Clinical criteria:

The condition must be due to idiopathic overactive bladder,

AND

The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents,

AND

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,

AND

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,

AND

Patient must be willing and able to self-catheterise.

Population criteria:
### SECTION 100 (BOTULINUM TOXIN PROGRAM)

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<tr>
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<td>6103F</td>
<td>botulinum toxin type A 100 units injection, 1 x 100 units vial</td>
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<td>Botox AG</td>
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**CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Criteria for availability**
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
Patient must be an adult.
Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.
Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.
Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Dynamic equinus foot deformity

**Clinical criteria:**
The condition must be due to spasticity,

**Population criteria:**
Patient must be an ambulant cerebral palsy patient.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.
SECTION 100 (BOTULINUM TOXIN PROGRAM)

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<td><strong>Criteria for availability</strong></td>
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<tr>
<td></td>
<td>Spasmodic torticollis</td>
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<td><strong>Clinical criteria:</strong></td>
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<td>The treatment must be as monotherapy; OR</td>
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<td>The treatment must be as adjunctive therapy to current standard care.</td>
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<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Criteria for availability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blepharospasm or hemifacial spasm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Population criteria:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient must be an adult.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Note</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</td>
<td></td>
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<td></td>
<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</td>
<td></td>
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</tbody>
</table>

1152P  
clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial  
1  
361.52  
Dysport  
IS

6293F  
clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial  
1  
644.81  
Dysport  
IS

**INCOBOTULINUMTOXINA**

**Criteria for availability**
Spasmodic torticollis

**Clinical criteria:**
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

**Criteria for availability**
Blepharospasm

**Population criteria:**
Patient must be an adult.

**Criteria for availability**
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
Patient must be an adult.

Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.

Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.
Contraindications to treatment include established severe contracture and known sensitivity to botulinum neurotoxin.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

10253P  
incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial  
1  
375.00  
Xeomin  
EZ
SECTION 100 (HUMAN GROWTH HORMONE)

**SOMATROPIN**

**Criteria for availability**

Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

(i) short stature and slow growth;
(ii) short stature associated with biochemical growth hormone deficiency;
(iii) growth retardation secondary to intracranial lesion or cranial irradiation;
(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
(v) short stature associated with Turner Syndrome;
(vi) short stature due to short stature homeobox (SHOX) gene disorders;
(vii) short stature associated with chronic renal insufficiency;
(viii) biochemical growth hormone deficiency and precocious puberty;
(ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines.

**Note**

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing’s internet site at http://www.health.gov.au/hGH, or from:

Growth Hormone Program
Access and Systems Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

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<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>6329D</td>
<td>SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1</td>
<td>1</td>
<td>396.00</td>
<td>Saizen 8 mg click.easy SG</td>
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<tr>
<td>9586M</td>
<td>SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1</td>
<td>1</td>
<td>594.00</td>
<td>Genotropin GoQuick PF</td>
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<tr>
<td>9585L</td>
<td>SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1</td>
<td>1</td>
<td>247.50</td>
<td>Genotropin GoQuick PF</td>
</tr>
<tr>
<td>9628R</td>
<td>somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>207.90</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6266T</td>
<td>somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&amp;) inert substance diluent [1 vial], 1 pack</td>
<td>1</td>
<td>198.00</td>
<td>Zomacton FP</td>
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<td>6295H</td>
<td>somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>247.50</td>
<td>Norditropin SimpleXx NO</td>
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<td>6476W</td>
<td>somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>247.50</td>
<td>Omnitrope SZ</td>
</tr>
<tr>
<td>6169Q</td>
<td>somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (&amp;) inert substance diluent [1 x 3.15 mL syringe], 1 pack</td>
<td>1</td>
<td>297.00</td>
<td>Humatrope LY</td>
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<tr>
<td>5822K</td>
<td>somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge</td>
<td>1</td>
<td>297.00</td>
<td>Saizen SG</td>
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<td>6313G</td>
<td>somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>277.20</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6314H</td>
<td>somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>346.50</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6315J</td>
<td>somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>415.80</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6310D</td>
<td>somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&amp;) inert substance diluent [1 x 1 mL syringe], 1 pack</td>
<td>1</td>
<td>495.00</td>
<td>Zomacton FP</td>
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<tr>
<td>6296J</td>
<td>somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>Norditropin SimpleXx NO</td>
</tr>
<tr>
<td>6311E</td>
<td>somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>Omnitrope SZ</td>
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</table>
## SECTION 100 (HUMAN GROWTH HORMONE)

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<tbody>
<tr>
<td>9604L</td>
<td>somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>NutropinAq IS</td>
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<tr>
<td>6312F</td>
<td>somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (1 x inert substance diluent [1 x 1 mL cartridge], 1 pack)</td>
<td>1</td>
<td>594.00</td>
<td>Genotropin PF</td>
</tr>
<tr>
<td>6170R</td>
<td>somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (1 x inert substance diluent [1 x 3.15 mL syringe], 1 pack)</td>
<td>1</td>
<td>594.00</td>
<td>Humatrope LY</td>
</tr>
<tr>
<td>5824M</td>
<td>somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>594.00</td>
<td>Saizen SG</td>
</tr>
<tr>
<td>6316K</td>
<td>somatropin 4.2 international units (1 mg) injection [7 x 1.4 mg syringes] (1 x inert substance diluent [7 x 0.25 mL syringes], 1 pack)</td>
<td>1</td>
<td>485.10</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6317L</td>
<td>somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (1 x inert substance diluent [7 x 0.25 mL syringes], 1 pack)</td>
<td>1</td>
<td>554.40</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6297K</td>
<td>somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>742.50</td>
<td>Norditropin SimpleXx NO</td>
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<tr>
<td>6318M</td>
<td>somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (1 x inert substance diluent [7 x 0.25 mL syringes], 1 pack)</td>
<td>1</td>
<td>623.70</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6319N</td>
<td>somatropin 6 international units (2 mg) injection [7 x 0.25 mL syringes] (1 x inert substance diluent [7 x 0.25 mL syringes], 1 pack)</td>
<td>1</td>
<td>693.00</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>3388H</td>
<td>somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge</td>
<td>1</td>
<td>990.00</td>
<td>Saizen SG</td>
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<tr>
<td>6345Y</td>
<td>somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (1 x inert substance diluent [1 x 3.15 mL syringe], 1 pack)</td>
<td>1</td>
<td>1188.00</td>
<td>Humatrope LY</td>
</tr>
</tbody>
</table>

### SOMATROPIN

#### Criteria for availability

Short stature in accordance with the ‘Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

- (i) short stature and slow growth;
- (ii) short stature associated with biochemical growth hormone deficiency;
- (iii) growth retardation secondary to intracranial lesion or cranial irradiation;
- (iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
- (v) short stature associated with Turner Syndrome;
- (vi) short stature due to short stature homeobox (SHOX) gene disorders;
- (vii) short stature associated with chronic renal insufficiency;
- (viii) biochemical growth hormone deficiency and precocious puberty;
- (ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines.

#### Note

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing’s internet site at http://www.health.gov.au/hGH, or from:

**Growth Hormone Program**

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

**Note**

Special Pricing Arrangements apply.

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<tbody>
<tr>
<td>5818F</td>
<td>somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>315.50</td>
<td>Norditropin FlexPro NO</td>
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<tr>
<td>5819G</td>
<td>somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>631.00</td>
<td>Norditropin FlexPro NO</td>
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<tr>
<td>5820H</td>
<td>somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>946.50</td>
<td>Norditropin FlexPro NO</td>
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### SECTION 100 (IVF/GIFT TREATMENT)

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
</table>
| CETRORELIX | **Criteria for availability**  
For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | 1 | 46.08 | Cetrotide SG |
| CHORIOGONADOTROPIN ALFA | **Criteria for availability**  
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | 1 | 54.80 | Ovidrel SG |
| CORIFOLLITROPIN ALFA | **Criteria for availability**  
Controlled ovarian stimulation  
**Clinical criteria:**  
Patient must have an antral follicle count of 20 or less.  
**Treatment criteria:**  
Patient must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations,  
**AND**  
Patient must be undergoing a gonadotrophin releasing hormone antagonist cycle. | 1 | 410.14 | Elonva MK |
| 5817E | follitropin alfa 150 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 673.51 | Elonva MK |
| 6433N | follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 435.60 | Gonal-f Pen SG |
| FOLLITROPIN ALFA | **Criteria for availability**  
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | 1 | 145.20 | Gonal-f Pen SG |
<p>| 6432M | follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge | 1 | 217.80 | Gonal-f Pen SG |
| 6335K | follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL | 1 | 150.00 | Puregon 300 IU/0.36 MK |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>6336L</td>
<td>follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge</td>
<td>1</td>
<td>292.72 $/ml</td>
<td>Puregon 600 IU/0.72 mL MK</td>
</tr>
<tr>
<td>6464F</td>
<td>follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge</td>
<td>1</td>
<td>435.15 $/ml</td>
<td>Puregon 900 IU/1.08 mL MK</td>
</tr>
</tbody>
</table>

**GANIRELIX**

**Criteria for availability**
For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>9583J</td>
<td>ganirelix 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1</td>
<td>46.08 $/mg</td>
<td>Orgalutran MK</td>
</tr>
<tr>
<td>9584K</td>
<td>ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes</td>
<td>1</td>
<td>230.40 $/mg</td>
<td>Orgalutran MK</td>
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</tbody>
</table>

**GONADOTROPHIN CHORIONIC HUMAN**

**Criteria for availability**
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

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<tbody>
<tr>
<td>6178E</td>
<td>gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&amp;) inert substance diluent [3 x 1 mL ampoules], 1 pack</td>
<td>1</td>
<td>39.57 $/mg</td>
<td>Pregnyl MK</td>
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<tr>
<td>6181H</td>
<td>gonadotrophin chorionic human 5000 international units injection [1 x 5000 international units ampoule] (&amp;) inert substance diluent [1 x 1 mL ampoule], 1 pack</td>
<td>1</td>
<td>11.49 $/mg</td>
<td>Pregnyl MK</td>
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**GONADOTROPHIN-MENOPAUSAL HUMAN**

**Criteria for availability**
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

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<tbody>
<tr>
<td>2038G</td>
<td>gonadotrophin-menopausal human 1200 international units injection [1 x 1200 international units vial] (&amp;) inert substance diluent [2 x 1 mL syringes], 1 pack</td>
<td>1</td>
<td>531.18 $/mg</td>
<td>Menopur 1200 FP</td>
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<tr>
<td>2036E</td>
<td>gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] (&amp;) inert substance diluent [1 x 1 mL syringe], 1 pack</td>
<td>1</td>
<td>265.59 $/mg</td>
<td>Menopur 600 FP</td>
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**NAFARELIN**

**Criteria for availability**
For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Note**
Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

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<tbody>
<tr>
<td>5815C</td>
<td>nafarelin 200 microgram/actuation nasal spray, 60 actuations</td>
<td>1</td>
<td>106.00 $/actuation</td>
<td>Synarel PF</td>
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</table>

**PROGESTERONE**

**Criteria for availability**
Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women.

**Clinical criteria:**
The treatment must be for luteal phase support,

**AND**
Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**Note**
### SECTION 100 (IVF/GIFT TREATMENT)

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<tbody>
<tr>
<td>9608Q</td>
<td>progesterone 100 mg pessary, 15</td>
<td>1</td>
<td>50.40</td>
<td>Oripro</td>
</tr>
<tr>
<td>10116K</td>
<td>progesterone 100 mg pessary, 21</td>
<td>1</td>
<td>49.39</td>
<td>Endometrin</td>
</tr>
<tr>
<td>9609R</td>
<td>progesterone 200 mg pessary, 15</td>
<td>1</td>
<td>55.60</td>
<td>Oripro</td>
</tr>
<tr>
<td>6366C</td>
<td>progesterone 8% vaginal gel, 15 applications</td>
<td>1</td>
<td>148.50</td>
<td>Crinone 8%</td>
</tr>
</tbody>
</table>

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.

### PROGESTERONE

**Criteria for availability**

Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women

**Clinical criteria:**

- The treatment must be for luteal phase support,
- **AND**
- Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.
- The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**Note**

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.

**Note**

Special Pricing Arrangements apply.
## OPIATE DEPENDENCE TREATMENT PROGRAM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>BUPRENORPHINE</td>
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<tr>
<td>Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment</td>
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<tr>
<td><strong>Note</strong> Treatment must be in accordance with the law of the relevant State or Territory.</td>
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<tr>
<td><strong>Note</strong> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<th>Brand Name and Manufacturer</th>
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<td>buprenorphine 2 mg tablet, 7</td>
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<td>RC</td>
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<td>6307Y</td>
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<td>6.16</td>
<td>Subutex</td>
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<tr>
<td>NP</td>
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</tr>
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<td>6309C</td>
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<td>30.10</td>
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<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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<td>Treatment of opiate dependence within a framework of medical, social and psychological treatment</td>
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<tr>
<td><strong>Caution</strong> Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.</td>
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<tr>
<td><strong>Note</strong> Treatment must be in accordance with the law of the relevant State or Territory.</td>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>9749D</td>
<td>buprenorphine 2 mg + naloxone 500 microgram film: sublingual, 28 films</td>
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<td>46.20</td>
<td>Suboxone Film 2/0.5</td>
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<td>RC</td>
</tr>
<tr>
<td>9750E</td>
<td>buprenorphine 8 mg + naloxone 2 mg film: sublingual, 28 films</td>
<td>1</td>
<td>132.44</td>
<td>Suboxone Film 8/2</td>
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<td>NP</td>
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<td></td>
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<td>RC</td>
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<th>Price ex manufacturer $</th>
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<td>Treatment of opiate dependence in accordance with the law of the relevant State or Territory</td>
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<tr>
<td><strong>Caution</strong> The risk of drug dependence is high.</td>
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<tr>
<td><strong>Note</strong> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>6172W</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 1000 mL</td>
<td>1</td>
<td>33.20</td>
<td>Aspen Methadone Syrup</td>
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<tr>
<td>NP</td>
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<td></td>
<td></td>
<td>QA</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>a Biodone Forte</td>
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<tr>
<td>6171T</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>7.91</td>
<td>Aspen Methadone Syrup</td>
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<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td>QA</td>
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<tr>
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<td>a Biodone Forte</td>
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Section 3 – Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Description</th>
<th>Price</th>
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<tbody>
<tr>
<td>Injectables</td>
<td>150 mL vial</td>
<td>$0.81</td>
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<tr>
<td>Other Items</td>
<td>25 mL vial</td>
<td>$0.32</td>
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(The 25 mL is the most commonly used size)

FEES:

- Dispensing Fee for Ready Prepared Benefits: $6.76
- Dangerous Drug Fee: $2.71
- Additional Fee for Agreed Price Ready Prepared Benefits: $1.15

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 2 of the Schedule.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Form/Strength</th>
<th>Pack and Price</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8048N</td>
<td>abciximab 10 mg/5 mL injection, 1 x 5 mL vial</td>
<td>1@ 482.23</td>
<td>LY</td>
</tr>
<tr>
<td>1003T</td>
<td>aciclovir 200 mg tablet, 25</td>
<td>25@ 12.83</td>
<td>AF, GN, SZ</td>
</tr>
<tr>
<td>1003T</td>
<td>aciclovir 200 mg tablet, 25</td>
<td>25@ 13.86</td>
<td>GK</td>
</tr>
<tr>
<td>2014B</td>
<td>alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL</td>
<td>1@ 4.13</td>
<td>RC</td>
</tr>
<tr>
<td>1557Y</td>
<td>allopurinol 100 mg tablet, 100</td>
<td>100@ 2.28</td>
<td>AF</td>
</tr>
<tr>
<td>2159P</td>
<td>aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL</td>
<td>1@ 5.64</td>
<td>FM</td>
</tr>
<tr>
<td>3417W</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>9330C</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>8678R</td>
<td>amino acid formula without phenylalanine 1 g tablet, 75</td>
<td>1@ 59.19</td>
<td>SB</td>
</tr>
<tr>
<td>8554F</td>
<td>amino acid formula without phenylalanine 500 mg capsule, 200</td>
<td>1@ 79.37</td>
<td>SB</td>
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<tr>
<td>2347M</td>
<td>amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets</td>
<td>1@ 208.07</td>
<td>SB</td>
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<tr>
<td>10161T</td>
<td>amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets</td>
<td>1@ 257.66</td>
<td>VF</td>
</tr>
<tr>
<td>8479G</td>
<td>amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g</td>
<td>1@ 87.15</td>
<td>SB</td>
</tr>
<tr>
<td>9438R</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
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<tr>
<td>5484P</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 787.00</td>
<td>VF</td>
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<tr>
<td>2650L</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>2646G</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>3444G</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>3443F</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>8058D</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>8059E</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>8061G</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>1923F</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>9133Q</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>2640Y</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets</td>
<td>1@ 1018.99</td>
<td>VF</td>
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<tr>
<td>2639X</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8677Q</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
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<tr>
<td>8744F</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
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<tr>
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<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>8328H</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
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<tr>
<td>8416Y</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 337.29</td>
<td>SB</td>
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<tr>
<td>1548L</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 1030.64</td>
<td>SB</td>
</tr>
<tr>
<td>9132P</td>
<td>amino acid formula with vitamins and minerals without phenylalanine</td>
<td>1@ 772.99</td>
<td>VF</td>
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<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<tr>
<td>2701E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans</td>
<td>1@ 1018.99</td>
<td>VF</td>
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<tr>
<td>2674R</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL cans</td>
<td>1@ 526.99</td>
<td>VF</td>
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<tr>
<td>8631G</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
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<td>8667E</td>
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<td>1@ 772.99</td>
<td>VF</td>
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<tr>
<td>9395L</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets</td>
<td>1@ 448.51</td>
<td>SB</td>
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<tr>
<td>8445L</td>
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<td>1@ 95.36</td>
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<td>SB</td>
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<tr>
<td>8446M</td>
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<td>1@ 222.29</td>
<td>SB</td>
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<td>8746H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans</td>
<td>18@ 261.37</td>
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<td>9021T</td>
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<td>1@ 514.34</td>
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<tr>
<td>8846N</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans</td>
<td>1@ 385.48</td>
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<td>1@ 511.90</td>
<td>VF</td>
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<td>5483N</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets</td>
<td>1@ 263.05</td>
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<tr>
<td>2382J</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans</td>
<td>1@ 257.09</td>
<td>VF</td>
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<tr>
<td>9396M</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans</td>
<td>1@ 315.86</td>
<td>SB</td>
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<tr>
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<td>1@ 526.47</td>
<td>SB</td>
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<tr>
<td>8555G</td>
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<td>1@ 263.05</td>
<td>VF</td>
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<td>8591E</td>
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<td>1@ 385.68</td>
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<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets</td>
<td>1@ 514.34</td>
<td>SB</td>
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<td>8613H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets</td>
<td>1@ 221.42</td>
<td>SB</td>
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<tr>
<td>8727H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets</td>
<td>1@ 514.34</td>
<td>SB</td>
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<tr>
<td>2738D</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g</td>
<td>1@ 168.25</td>
<td>SB</td>
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<td>2739E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars</td>
<td>1@ 615.44</td>
<td>SB</td>
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<tr>
<td>1411G</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1</td>
<td>1@ 544.55</td>
<td>SB</td>
</tr>
<tr>
<td>1909L</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1</td>
<td>1@ 511.90</td>
<td>VF</td>
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<tr>
<td>2375B</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>2654Q</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches</td>
<td>1@ 1018.99</td>
<td>VF</td>
</tr>
<tr>
<td>2651M</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8592F</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8632H</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>8745G</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets</td>
<td>1@ 448.51</td>
<td>SB</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
<tr>
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</tr>
<tr>
<td>2380G</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>8057C</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>8260R</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 1021.93</td>
<td>VF</td>
</tr>
<tr>
<td>1546J</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>1180D</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>1914R</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 1021.93</td>
<td>VF</td>
</tr>
<tr>
<td>9499Y</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>2900P</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>NT</td>
</tr>
<tr>
<td>2928D</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>NT</td>
</tr>
<tr>
<td>5466Q</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>5467R</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>2246F</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>2560R</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>9339M</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>AB</td>
</tr>
<tr>
<td>9340N</td>
<td>amino acid synthetic formula oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>AB</td>
</tr>
<tr>
<td>8736T</td>
<td>amidopurine modified long chain oral liquid: powder for, 30 x 60 g sachets</td>
<td>1@ 71.16</td>
<td>SW</td>
</tr>
<tr>
<td>9386B</td>
<td>amidopurine modified long chain oral liquid: powder for, 30 x 60 g sachets</td>
<td>1@ 186.47</td>
<td>VF</td>
</tr>
<tr>
<td>10036F</td>
<td>arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 91.10</td>
<td>VF</td>
</tr>
<tr>
<td>5482M</td>
<td>arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 191.10</td>
<td>VF</td>
</tr>
<tr>
<td>9437Q</td>
<td>arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
</tr>
<tr>
<td>10093F</td>
<td>arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 254.17</td>
<td>VF</td>
</tr>
<tr>
<td>9092M</td>
<td>atomoxetine 10 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9093N</td>
<td>atomoxetine 18 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9094P</td>
<td>atomoxetine 25 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9095Q</td>
<td>atomoxetine 40 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9096R</td>
<td>atomoxetine 60 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>1140B</td>
<td>Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (G) inert substance diluent [1 x 3 mL vial], 1 pack</td>
<td>1@ 151.15</td>
<td>SW</td>
</tr>
<tr>
<td>2647H</td>
<td>benzylpenicillin 3 g injection, 1 x 3 g vial</td>
<td>1@ 8.31</td>
<td>CS</td>
</tr>
<tr>
<td>3399X</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 8.31</td>
<td>CS</td>
</tr>
<tr>
<td>1775K</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 4.83</td>
<td>CS</td>
</tr>
<tr>
<td>3398W</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 4.83</td>
<td>CS</td>
</tr>
<tr>
<td>2812B</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 8.90</td>
<td>FM, FR</td>
</tr>
<tr>
<td>2812B</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 10.13</td>
<td>MK</td>
</tr>
<tr>
<td>2812B</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 12.34</td>
<td>QA</td>
</tr>
<tr>
<td>2544X</td>
<td>biperiden hydrochloride 2 mg tablet, 100</td>
<td>1@ 7.23</td>
<td>LM</td>
</tr>
<tr>
<td>1260H</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>1@ 4.84</td>
<td>PP</td>
</tr>
<tr>
<td>1260H</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>1@ 5.34</td>
<td>BY</td>
</tr>
<tr>
<td>5303D</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>1@ 4.84</td>
<td>PP</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>5307H</td>
<td>1@ 5.34</td>
<td></td>
<td>BY</td>
</tr>
<tr>
<td>5307H</td>
<td>1@ 4.84</td>
<td></td>
<td>PP</td>
</tr>
<tr>
<td>1258F</td>
<td>bisacodyl 10 mg suppository, 12</td>
<td>1@ 3.97</td>
<td>PP</td>
</tr>
<tr>
<td>5304E</td>
<td>1@ 3.97</td>
<td></td>
<td>PP</td>
</tr>
<tr>
<td>5308J</td>
<td>1@ 3.97</td>
<td></td>
<td>PP</td>
</tr>
<tr>
<td>1443Y</td>
<td>bromocriptine 2.5 mg tablet, 30</td>
<td>30@ 12.50</td>
<td>NV</td>
</tr>
<tr>
<td>10015D</td>
<td>budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>1@ 26.17</td>
<td>AP</td>
</tr>
<tr>
<td>10018G</td>
<td>budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>1@ 41.32</td>
<td>AP</td>
</tr>
<tr>
<td>3116B</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>60@ 5.62</td>
<td>IA, PP</td>
</tr>
<tr>
<td>2422L</td>
<td>CARBAMAZEPINE Tablet 100 mg, 100</td>
<td>100@ 6.04</td>
<td>SZ</td>
</tr>
<tr>
<td>2422L</td>
<td>CARBAMAZEPINE Tablet 100 mg, 100</td>
<td>100@ 7.52</td>
<td>NV</td>
</tr>
<tr>
<td>5039F</td>
<td>100@ 6.04</td>
<td></td>
<td>SZ</td>
</tr>
<tr>
<td>1706T</td>
<td>CARBAMAZEPINE Tablet 200 mg, 100</td>
<td>100@ 11.29</td>
<td>SZ</td>
</tr>
<tr>
<td>1724R</td>
<td>CARBAMAZEPINE Tablet 200 mg, 100</td>
<td>100@ 12.77</td>
<td>NV</td>
</tr>
<tr>
<td>1724R</td>
<td>CARBAMAZEPINE Tablet 200 mg, 100</td>
<td>100@ 12.77</td>
<td>NV</td>
</tr>
<tr>
<td>1153Q</td>
<td>carbimazole 5 mg tablet, 100</td>
<td>100@ 12.31</td>
<td>LM, PQ</td>
</tr>
<tr>
<td>8369L</td>
<td>carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g</td>
<td>1@ 38.97</td>
<td>SB</td>
</tr>
<tr>
<td>10050Y</td>
<td>carbohydrates, fat, vitamins, minerals, trace elements supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets</td>
<td>1@ 60.46</td>
<td>VF</td>
</tr>
<tr>
<td>10039J</td>
<td>carbohydrates, fat, vitamins, minerals, trace elements supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 43 g sachets</td>
<td>1@ 116.43</td>
<td>VF</td>
</tr>
<tr>
<td>2058H</td>
<td>carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses</td>
<td>1@ 9.89</td>
<td>BU</td>
</tr>
<tr>
<td>2090B</td>
<td>carbomer-974 0.3% eye gel, 30 x 500 mg unit doses</td>
<td>1@ 9.88</td>
<td>BU</td>
</tr>
<tr>
<td>5502N</td>
<td>carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses</td>
<td>1@ 9.89</td>
<td>AQ</td>
</tr>
<tr>
<td>8514D</td>
<td>carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses</td>
<td>1@ 9.89</td>
<td>AQ</td>
</tr>
<tr>
<td>5509Y</td>
<td>carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses</td>
<td>1@ 8.50</td>
<td>CX</td>
</tr>
<tr>
<td>8823J</td>
<td>carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 8.50</td>
<td>CX</td>
</tr>
<tr>
<td>2338C</td>
<td>carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 8.29</td>
<td>PP</td>
</tr>
<tr>
<td>5506T</td>
<td>carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 9.88</td>
<td>AG</td>
</tr>
<tr>
<td>5561Q</td>
<td>carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 9.88</td>
<td>AG</td>
</tr>
<tr>
<td>9307W</td>
<td>carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 9.88</td>
<td>AG</td>
</tr>
<tr>
<td>2324H</td>
<td>carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 8.29</td>
<td>PP</td>
</tr>
<tr>
<td>1086D</td>
<td>cefotaxime 1 g injection, 1 x 1 g vial</td>
<td>1@ 1.47</td>
<td>SZ</td>
</tr>
<tr>
<td>5048Q</td>
<td>cefotaxime 2 g injection, 1 x 2 g vial</td>
<td>1@ 2.73</td>
<td>SZ</td>
</tr>
<tr>
<td>1784X</td>
<td>cefotaxime 1 g injection, 1 x 1 g vial</td>
<td>1@ 1.38</td>
<td>AE, HH, PP, SZ</td>
</tr>
<tr>
<td>1785Y</td>
<td>cefotaxime 2 g injection, 1 x 2 g vial</td>
<td>1@ 2.56</td>
<td>AE, AF, HH, SZ</td>
</tr>
<tr>
<td>1783W</td>
<td>cefotaxime 500 mg injection, 1 x 500 mg vial</td>
<td>1@ 0.87</td>
<td>AE, PP</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Price</td>
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</tr>
<tr>
<td>2655R</td>
<td>cephalixin 250 mg capsule, 20</td>
<td>20</td>
<td>1.13</td>
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<tr>
<td>1799Q</td>
<td>cephalixin 1 g injection, 5 x 1 g vials</td>
<td>5</td>
<td>3.73</td>
</tr>
<tr>
<td>1799Q</td>
<td>cephalixin 1 g injection, 5 x 1 g vials</td>
<td>5</td>
<td>3.73</td>
</tr>
<tr>
<td>5479J</td>
<td>cephalxin 2 g injection, 1 x 2 g vial</td>
<td>1</td>
<td>1.70</td>
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<tr>
<td>9326W</td>
<td>cephalxin 250 mg injection, 5 x 500 mg vials</td>
<td>5</td>
<td>2.81</td>
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<tr>
<td>1163F</td>
<td>chlorambucil 2 mg tablet, 25</td>
<td>25</td>
<td>36.84</td>
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<tr>
<td>1585K</td>
<td>chlorothalidone 25 mg tablet, 50</td>
<td>50</td>
<td>5.58</td>
</tr>
<tr>
<td>2957E</td>
<td>cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets</td>
<td>1</td>
<td>32.76</td>
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<tr>
<td>1217C</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1</td>
<td>12.06</td>
</tr>
<tr>
<td>1217C</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1</td>
<td>11.03</td>
</tr>
<tr>
<td>5564W</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1</td>
<td>12.06</td>
</tr>
<tr>
<td>5564W</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1</td>
<td>11.03</td>
</tr>
<tr>
<td>5481L</td>
<td>citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets</td>
<td>1</td>
<td>127.40</td>
</tr>
<tr>
<td>1808E</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>1</td>
<td>4.31</td>
</tr>
<tr>
<td>5339B</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>1</td>
<td>4.31</td>
</tr>
<tr>
<td>5342E</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>1</td>
<td>4.31</td>
</tr>
<tr>
<td>1806C</td>
<td>clonazepam 2 mg tablet, 100</td>
<td>100</td>
<td>14.25</td>
</tr>
<tr>
<td>1806C</td>
<td>clonazepam 2 mg tablet, 100</td>
<td>100</td>
<td>12.32</td>
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<tr>
<td>1805B</td>
<td>clonazepam 500 microgram tablet, 100</td>
<td>100</td>
<td>8.25</td>
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<tr>
<td>1805B</td>
<td>clonazepam 500 microgram tablet, 100</td>
<td>100</td>
<td>6.54</td>
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<tr>
<td>8785J</td>
<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
<td>20</td>
<td>0.92</td>
</tr>
<tr>
<td>8785J</td>
<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
<td>20</td>
<td>3.32</td>
</tr>
<tr>
<td>8661W</td>
<td>cyclosporin 100 mg/mL oral liquid, 50 mL</td>
<td>1</td>
<td>353.12</td>
</tr>
<tr>
<td>8660T</td>
<td>cyclosporin 100 mg capsule, 30</td>
<td>30</td>
<td>184.01</td>
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<tr>
<td>8657P</td>
<td>cyclosporin 10 mg capsule, 60</td>
<td>60</td>
<td>44.00</td>
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<tr>
<td>8658Q</td>
<td>cyclosporin 25 mg capsule, 30</td>
<td>30</td>
<td>45.41</td>
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<tr>
<td>8659R</td>
<td>cyclosporin 50 mg capsule, 30</td>
<td>30</td>
<td>94.48</td>
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<tr>
<td>1270W</td>
<td>cyproterone acetate 50 mg tablet, 50</td>
<td>50</td>
<td>50.30</td>
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<tr>
<td>1270W</td>
<td>cyproterone acetate 50 mg tablet, 50</td>
<td>50</td>
<td>51.24</td>
</tr>
<tr>
<td>9164H</td>
<td>cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1</td>
<td>127.40</td>
</tr>
<tr>
<td>9319L</td>
<td>dabigatran etexilate 110 mg capsule, 10</td>
<td>10</td>
<td>15.59</td>
</tr>
<tr>
<td>9323Q</td>
<td>dabigatran etexilate 110 mg capsule, 10</td>
<td>10</td>
<td>15.59</td>
</tr>
<tr>
<td>9318K</td>
<td>dabigatran etexilate 75 mg capsule, 10</td>
<td>10</td>
<td>19.56</td>
</tr>
<tr>
<td>9322P</td>
<td>dabigatran etexilate 75 mg capsule, 10</td>
<td>10</td>
<td>19.56</td>
</tr>
<tr>
<td>8959M</td>
<td>DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10</td>
<td>10</td>
<td>136.11</td>
</tr>
<tr>
<td>8960N</td>
<td>DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10</td>
<td>10</td>
<td>162.39</td>
</tr>
<tr>
<td>1229Q</td>
<td>dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes</td>
<td>10</td>
<td>84.57</td>
</tr>
<tr>
<td>8957K</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
<td>10</td>
<td>82.88</td>
</tr>
<tr>
<td>1296F</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
<td>10</td>
<td>117.43</td>
</tr>
<tr>
<td>8958L</td>
<td>dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10</td>
<td>114.43</td>
</tr>
<tr>
<td>8603T</td>
<td>dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10</td>
<td>49.16</td>
</tr>
<tr>
<td>8641T</td>
<td>dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10</td>
<td>49.16</td>
</tr>
<tr>
<td>8642W</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>10</td>
<td>51.23</td>
</tr>
<tr>
<td>8643X</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>10</td>
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<td>8956J</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>10</td>
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<td>Code</td>
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<td>Pack and Price</td>
<td>Manufacturer</td>
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<tr>
<td>2129C</td>
<td>desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL</td>
<td>1@ 30.95</td>
<td>FP</td>
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<tr>
<td>8711L</td>
<td>desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations</td>
<td>1@ 77.31</td>
<td>FP</td>
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<td>8662X</td>
<td>desmopressin acetate 200 microgram tablet, 30</td>
<td>30@ 57.83</td>
<td>FP</td>
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<tr>
<td>5521N</td>
<td>dextro-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses</td>
<td>1@ 9.55</td>
<td>AQ</td>
</tr>
<tr>
<td>8299T</td>
<td></td>
<td>1@ 9.55</td>
<td>AQ</td>
</tr>
<tr>
<td>1302M</td>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
<tr>
<td>5079H</td>
<td>diclofenac sodium 200 microgram tablet, 30</td>
<td>20@ 9.25</td>
<td>NV</td>
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<tr>
<td>5363G</td>
<td></td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
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<td>5366K</td>
<td></td>
<td>20@ 9.25</td>
<td>NV</td>
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<td>1259J</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>50@ 2.65</td>
<td>NV</td>
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<td>1259J</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
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<td>50@ 2.65</td>
<td>NV</td>
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<td>50@ 2.65</td>
<td>NV</td>
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<td></td>
<td>50@ 2.65</td>
<td>NV</td>
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<td>50@ 1.93</td>
<td>AF, CH, EA, GN, QA, SZ, TW, TX</td>
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<td>3164M</td>
<td>digoxin 50 microgram/mL oral liquid, 60 mL</td>
<td>50@ 2.65</td>
<td>NV</td>
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<tr>
<td>10040K</td>
<td>docosahexaenoic acid with carbohydrate containing 200 mg oral liquid: powder for, 30 x 4g sachets</td>
<td>1@ 17.35</td>
<td>QA</td>
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<td>2703G</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>7@ 3.09</td>
<td>YN</td>
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<td>2703G</td>
<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>7@ 1.93</td>
<td>YT</td>
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<td>2702F</td>
<td>doxycycline 100 mg tablet, 7</td>
<td>7@ 1.09</td>
<td>AF, GN, QA</td>
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<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
<td>7@ 1.09</td>
<td>AF, EA, GN, QA</td>
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<tr>
<td>9107H</td>
<td></td>
<td>7@ 1.09</td>
<td>CH, GX, HX, TW</td>
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<td>9108J</td>
<td></td>
<td>7@ 1.09</td>
<td>CH, HX, TW</td>
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<tr>
<td>5435C</td>
<td>enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes</td>
<td>10@ 102.33</td>
<td>SW</td>
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<tr>
<td>8558K</td>
<td>enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10@ 49.16</td>
<td>SW</td>
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<tr>
<td>8716R</td>
<td></td>
<td>10@ 49.16</td>
<td>SW</td>
</tr>
<tr>
<td>9195Y</td>
<td>enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules</td>
<td>10@ 51.23</td>
<td>SW</td>
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<tr>
<td>9196B</td>
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<td>10@ 51.23</td>
<td>SW</td>
</tr>
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<td>8510X</td>
<td>enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes</td>
<td>10@ 51.23</td>
<td>SW</td>
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<td>8639Q</td>
<td></td>
<td>10@ 51.23</td>
<td>SW</td>
</tr>
<tr>
<td>8640R</td>
<td>enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes</td>
<td>10@ 73.26</td>
<td>SW</td>
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<td>5434B</td>
<td>enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes</td>
<td>10@ 84.28</td>
<td>SW</td>
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<tr>
<td>8367J</td>
<td>entacapone 200 mg tablet, 100</td>
<td>100@ 137.70</td>
<td>NV</td>
</tr>
<tr>
<td>8397Y</td>
<td>eprosartan 400 mg tablet, 28</td>
<td>28@ 8.86</td>
<td>GO</td>
</tr>
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<td>8951D</td>
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<td>28@ 8.86</td>
<td>GO</td>
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<tr>
<td>8683B</td>
<td>eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial</td>
<td>1@ 128.06</td>
<td>MK</td>
</tr>
<tr>
<td>8684C</td>
<td>eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial</td>
<td>1@ 337.98</td>
<td>MK</td>
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<td>1397M</td>
<td>erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial</td>
<td>1@ 38.01</td>
<td>LM</td>
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<td>5088T</td>
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<td>1@ 38.01</td>
<td>LM</td>
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<td>9329B</td>
<td>essential amino acids formula oral liquid: powder for, 2 x 200 g cans</td>
<td>1@ 199.02</td>
<td>SB</td>
</tr>
<tr>
<td>2027Q</td>
<td>essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g</td>
<td>1@ 125.55</td>
<td>SB</td>
</tr>
<tr>
<td>9385Y</td>
<td>essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets</td>
<td>1@ 377.52</td>
<td>VF</td>
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<td>1954W</td>
<td>etanercept 25 mg injection [4 x 25 mg vials] (&amp;) inert substance diluent [4 x 1 mL syringes], 1 pack</td>
<td>1@ 883.97</td>
<td>PF</td>
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<td>3445H</td>
<td></td>
<td>1@ 883.97</td>
<td>PF</td>
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<tr>
<td>3448L</td>
<td></td>
<td>1@ 883.97</td>
<td>PF</td>
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<td>PF</td>
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<td>1@ 883.97</td>
<td>PF</td>
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<td>PF</td>
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<td>1@ 883.97</td>
<td>PF</td>
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<tr>
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<td>1@ 883.97</td>
<td>PF</td>
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<td>9429G</td>
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<td>1@ 883.97</td>
<td>PF</td>
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<td>8748K</td>
<td>ethacrynic acid 25 mg tablet, 100</td>
<td>100@ 95.44</td>
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<td>9352F</td>
<td>everolimus 1 mg tablet, 60</td>
<td>60@ 1031.17</td>
<td>NV</td>
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<td>8842J</td>
<td>everolimus 750 microgram tablet, 60</td>
<td>60@ 786.10</td>
<td>NV</td>
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<td>5411T</td>
<td>FENTANYL Lozenge 1200 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
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<td>5412W</td>
<td>FENTANYL Lozenge 1600 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
</tr>
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<td>5407N</td>
<td>FENTANYL Lozenge 200 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
</tr>
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<td>5408P</td>
<td>FENTANYL Lozenge 400 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
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<td>5409Q</td>
<td>FENTANYL Lozenge 600 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
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<td>5410R</td>
<td>FENTANYL Lozenge 800 micrograms (as citrate), 30</td>
<td>30@ 285.15</td>
<td>OA</td>
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<td>1473M</td>
<td>fluconazole 100 mg/50 mL injection, 1 x 50 mL vial</td>
<td>1@ 2.25</td>
<td>AE, HX, SZ</td>
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<td>1474N</td>
<td>fluconazole 200 mg/100 mL injection, 1 x 100 mL vial</td>
<td>1@ 4.24</td>
<td>AE, AF, HX, SZ</td>
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<td>1433K</td>
<td>fludrocortisone acetate 100 microgram tablet, 100</td>
<td>100@ 20.04</td>
<td>QA</td>
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<td>2958Q</td>
<td>folic acid 500 microgram tablet, 100</td>
<td>100@ 2.46</td>
<td>AF, PP</td>
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<tr>
<td>1427P</td>
<td>folic acid 5 mg tablet, 100</td>
<td>100@ 3.80</td>
<td>AF</td>
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<td>9041W</td>
<td>folinic acid 100 mg/10 mL injection, 1 x 10 mL vial</td>
<td>1@ 14.00</td>
<td>HH, SZ</td>
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<td>8740B</td>
<td>folinic acid 300 mg/30 mL injection, 1 x 30 mL vial</td>
<td>1@ 5.18</td>
<td>HH</td>
</tr>
<tr>
<td>8713N</td>
<td>follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL injection, 1 x 0.5 mL cartridge</td>
<td>1@ 162.36</td>
<td>SG</td>
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<tr>
<td>8714P</td>
<td>follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL injection, 1 x 0.75 mL cartridge</td>
<td>1@ 243.55</td>
<td>SG</td>
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<td>8715Q</td>
<td>follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL injection, 1 x 1.5 mL cartridge</td>
<td>1@ 487.09</td>
<td>SG</td>
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<td>8565T</td>
<td>follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge</td>
<td>1@ 167.73</td>
<td>MK</td>
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<td>8566W</td>
<td>follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge</td>
<td>1@ 327.32</td>
<td>MK</td>
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<td>8871X</td>
<td>follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge</td>
<td>1@ 486.58</td>
<td>MK</td>
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<td>8775W</td>
<td>FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2</td>
<td>2@ 37.05</td>
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<td>1810G</td>
<td>frusemide 20 mg tablet, 50</td>
<td>50@ 0.77</td>
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<td>frusemide 20 mg tablet, 50</td>
<td>50@ 1.61</td>
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<td>8444K</td>
<td>gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag</td>
<td>1@ 13.11</td>
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<td>2245E</td>
<td>glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 1.84</td>
<td>BX</td>
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<td>5106R</td>
<td>glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 1.84</td>
<td>BX</td>
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<td>3106L</td>
<td>glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 5.44</td>
<td>RD</td>
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<td>3107M</td>
<td>glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 5.50</td>
<td>BN</td>
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<td>glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 5.44</td>
<td>RD</td>
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<td>glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 5.50</td>
<td>BN</td>
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<td>10139P</td>
<td>glucose indicator blood strip: diagnostic, 50</td>
<td>1@ 23.38</td>
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<td>1@ 23.38</td>
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<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>1@ 23.38</td>
<td>NA</td>
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<td>9278H</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>PB</td>
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<td>glucose indicator blood strip: diagnostic, 51 diagnostic strips</td>
<td>1@ 23.38</td>
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<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>QB</td>
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<td>1@ 23.38</td>
<td>QB</td>
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<td>1@ 23.38</td>
<td>EH</td>
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<td>1@ 23.38</td>
<td>EH</td>
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<td>9485F</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>OI</td>
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<tr>
<td>9486G</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>OI</td>
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<td>glucose indicator blood strip: diagnostic, 51 diagnostic strips</td>
<td>1@ 23.38</td>
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<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>BD</td>
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<tr>
<td>9298J</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>QB</td>
</tr>
<tr>
<td>9298J</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>1@ 23.38</td>
<td>QB</td>
</tr>
<tr>
<td>2556M</td>
<td>glycerol 1.4 g suppository, 12</td>
<td>1@ 4.93</td>
<td>PP</td>
</tr>
<tr>
<td>5312N</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>5313P</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>5315R</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>2557N</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>5311M</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>5314Q</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>1@ 5.13</td>
<td>PP</td>
</tr>
<tr>
<td>10195N</td>
<td>glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
</tr>
<tr>
<td>2712R</td>
<td>glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles</td>
<td>1@ 105.31</td>
<td>QH</td>
</tr>
<tr>
<td>2696X</td>
<td>glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g</td>
<td>1@ 61.43</td>
<td>QH</td>
</tr>
<tr>
<td>2644E</td>
<td>glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g</td>
<td>1@ 92.15</td>
<td>QH</td>
</tr>
<tr>
<td>2685H</td>
<td>glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets</td>
<td>1@ 368.34</td>
<td>QH</td>
</tr>
<tr>
<td>8728J</td>
<td>granisetron 2 mg tablet, 1</td>
<td>1@ 11.49</td>
<td>RO</td>
</tr>
<tr>
<td>1076P</td>
<td>heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial</td>
<td>1@ 31.15</td>
<td>HH</td>
</tr>
<tr>
<td>2652N</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
<td>1@ 42.96</td>
<td>SB</td>
</tr>
<tr>
<td>10185C</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
<td>1@ 196.11</td>
<td>SB</td>
</tr>
<tr>
<td>9446E</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
<td>1@ 42.96</td>
<td>SB</td>
</tr>
<tr>
<td>1640H</td>
<td>hydralazine hydrochloride 25 mg tablet, 100</td>
<td>100@ 5.44</td>
<td>AF</td>
</tr>
<tr>
<td>1639G</td>
<td>hydralazine hydrochloride 50 mg tablet, 100</td>
<td>100@ 6.30</td>
<td>AF</td>
</tr>
<tr>
<td>1486F</td>
<td>hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50</td>
<td>50@ 3.54</td>
<td>AS</td>
</tr>
<tr>
<td>1501B</td>
<td>hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (6) inert substance diluent [1 x 2 mL vial], 1 pack</td>
<td>1@ 5.64</td>
<td>PF</td>
</tr>
<tr>
<td>1510L</td>
<td>hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (6) inert substance diluent [1 x 2 mL vial], 1 pack</td>
<td>1@ 5.64</td>
<td>PF</td>
</tr>
<tr>
<td>5118J</td>
<td>hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (6) inert substance diluent [1 x 2 mL vial], 1 pack</td>
<td>1@ 5.64</td>
<td>PF</td>
</tr>
<tr>
<td>1511M</td>
<td>hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (6) inert substance diluent [1 x 2 mL vial], 1 pack</td>
<td>1@ 9.64</td>
<td>PF</td>
</tr>
<tr>
<td>5119K</td>
<td>hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g</td>
<td>1@ 9.64</td>
<td>PF</td>
</tr>
<tr>
<td>1502C</td>
<td>hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g</td>
<td>1@ 17.01</td>
<td>HM</td>
</tr>
<tr>
<td>9487H</td>
<td>HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1</td>
<td>1@ 13.11</td>
<td>PK</td>
</tr>
<tr>
<td>5317W</td>
<td>hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g</td>
<td>5@ 17.02</td>
<td>BY</td>
</tr>
<tr>
<td>5318X</td>
<td>hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g</td>
<td>5@ 17.02</td>
<td>BY</td>
</tr>
<tr>
<td>3190X</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>30@ 2.77</td>
<td>GO</td>
</tr>
<tr>
<td>5123P</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>30@ 2.77</td>
<td>GO</td>
</tr>
<tr>
<td>5368M</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>30@ 2.77</td>
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</tr>
<tr>
<td>5370P</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>30@ 2.77</td>
<td>GO</td>
</tr>
<tr>
<td>2448W</td>
<td>ibuprofen 400 mg capsule, 1</td>
<td>1@ 162.69</td>
<td>PF</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
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<td>------------------------------------------------------------------------------------</td>
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<tr>
<td>2446R</td>
<td>idarubicin hydrochloride 5 mg capsule, 1</td>
<td>1@ 87.06</td>
<td>PF</td>
</tr>
<tr>
<td>2757D</td>
<td>indomethacin 100 mg suppository, 20</td>
<td>20@ 8.04</td>
<td>AS</td>
</tr>
<tr>
<td>5128X</td>
<td>20@ 8.04</td>
<td>20@ 8.04</td>
<td>AS</td>
</tr>
<tr>
<td>5378C</td>
<td>20@ 8.04</td>
<td>20@ 8.04</td>
<td>AS</td>
</tr>
<tr>
<td>5380E</td>
<td>20@ 8.04</td>
<td>20@ 8.04</td>
<td>AS</td>
</tr>
<tr>
<td>2454E</td>
<td>indomethacin 25 mg capsule, 50</td>
<td>50@ 5.54</td>
<td>AS</td>
</tr>
<tr>
<td>2454E</td>
<td>indomethacin 25 mg capsule, 50</td>
<td>50@ 3.22</td>
<td>AF</td>
</tr>
<tr>
<td>5126T</td>
<td>50@ 5.54</td>
<td>50@ 3.22</td>
<td>AF</td>
</tr>
<tr>
<td>5377B</td>
<td>50@ 5.54</td>
<td>50@ 5.54</td>
<td>AS</td>
</tr>
<tr>
<td>5379C</td>
<td>50@ 3.22</td>
<td>50@ 3.22</td>
<td>AF</td>
</tr>
<tr>
<td>5379D</td>
<td>50@ 3.22</td>
<td>50@ 5.54</td>
<td>AS</td>
</tr>
<tr>
<td>8571D</td>
<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 30.57</td>
<td>NO</td>
</tr>
<tr>
<td>8435Y</td>
<td>insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 51.56</td>
<td>NF, NO</td>
</tr>
<tr>
<td>8609D</td>
<td>insulin aspart 30 international units/mL + insulin aspart protamine 70</td>
<td>1@ 51.56</td>
<td>NF, NO</td>
</tr>
<tr>
<td>9040T</td>
<td>insulin detemir 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 85.26</td>
<td>NF, NO</td>
</tr>
<tr>
<td>9039R</td>
<td>insulin glargine 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 85.26</td>
<td>AV, SW</td>
</tr>
<tr>
<td>9224L</td>
<td>insulin glulisine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 30.57</td>
<td>SW</td>
</tr>
<tr>
<td>1711C</td>
<td>insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 51.56</td>
<td>AV, SW</td>
</tr>
<tr>
<td>1533Q</td>
<td>insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 78.86</td>
<td>AS</td>
</tr>
<tr>
<td>1531N</td>
<td>insulin isophane human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 25.48</td>
<td>LY, NO</td>
</tr>
<tr>
<td>1531N</td>
<td>insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 43.58</td>
<td>LY, NI, NO</td>
</tr>
<tr>
<td>1763T</td>
<td>insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 43.58</td>
<td>LY, NI, NO</td>
</tr>
<tr>
<td>8084L</td>
<td>insulin lispro 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 30.57</td>
<td>LY</td>
</tr>
<tr>
<td>8212F</td>
<td>insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
</tr>
<tr>
<td>8390N</td>
<td>insulin lispro 25 international units/mL + insulin lispro protamine 75 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
</tr>
<tr>
<td>8874C</td>
<td>insulin lispro 50 international units/mL + insulin lispro protamine 50 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
</tr>
<tr>
<td>1713E</td>
<td>insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 78.86</td>
<td>AS</td>
</tr>
<tr>
<td>1751N</td>
<td>insulin neutral human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 25.48</td>
<td>LY, NO</td>
</tr>
<tr>
<td>1762R</td>
<td>insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 43.58</td>
<td>LY, NO</td>
</tr>
<tr>
<td>1426C</td>
<td>insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 25.48</td>
<td>LY</td>
</tr>
<tr>
<td>2062M</td>
<td>insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges</td>
<td>1@ 43.58</td>
<td>NO</td>
</tr>
<tr>
<td>8180M</td>
<td>interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 33.32</td>
<td>RO</td>
</tr>
<tr>
<td>8181N</td>
<td>interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 33.32</td>
<td>RO</td>
</tr>
<tr>
<td>8182P</td>
<td>interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 51.66</td>
<td>RO</td>
</tr>
<tr>
<td>8551C</td>
<td>interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 51.66</td>
<td>RO</td>
</tr>
<tr>
<td>8183Q</td>
<td>interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 67.66</td>
<td>RO</td>
</tr>
<tr>
<td>8552D</td>
<td>interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 67.66</td>
<td>RO</td>
</tr>
<tr>
<td>8184R</td>
<td>interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1@ 99.94</td>
<td>RO</td>
</tr>
<tr>
<td>8553E</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 99.94</td>
<td>RO</td>
</tr>
<tr>
<td>8348J</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 199.87</td>
<td>MK</td>
</tr>
<tr>
<td>8572E</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 199.87</td>
<td>MK</td>
</tr>
<tr>
<td>8476D</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 333.11</td>
<td>MK</td>
</tr>
<tr>
<td>8671J</td>
<td>ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations</td>
<td>1@ 13.71</td>
<td>BY</td>
</tr>
<tr>
<td>1542E</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL</td>
<td>1@ 10.76</td>
<td>AF, QA, TX</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
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<td>--------</td>
<td>--------------------------------------------------------</td>
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<td>--------------</td>
</tr>
<tr>
<td>1542E</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 11.02</td>
<td>BY</td>
</tr>
<tr>
<td>8238N</td>
<td>ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 12.72</td>
<td>AF, QA, TX</td>
</tr>
<tr>
<td>8238N</td>
<td>ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 12.96</td>
<td>BY</td>
</tr>
<tr>
<td>10104T</td>
<td>iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial</td>
<td>1@ 155.23</td>
<td>VL</td>
</tr>
<tr>
<td>9436P</td>
<td>isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 140.14</td>
<td>VF</td>
</tr>
<tr>
<td>9134R</td>
<td>isoleucine with carbohydrate containing 50 g isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
</tr>
<tr>
<td>2588F</td>
<td>losartan potassium 50 mg tablet: sublingual, 100</td>
<td>100@ 4.07</td>
<td>QA</td>
</tr>
<tr>
<td>2868Y</td>
<td>ivermectin 3 mg tablet, 4</td>
<td>4@ 23.89</td>
<td>MK</td>
</tr>
<tr>
<td>1588N</td>
<td>ketoprofen 100 mg suppository, 20</td>
<td>20@ 9.44</td>
<td>SW</td>
</tr>
<tr>
<td>5139L</td>
<td>ketoprofen 100 mg suppository, 20</td>
<td>20@ 9.44</td>
<td>SW</td>
</tr>
<tr>
<td>2286H</td>
<td>lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 3.94</td>
<td>QA</td>
</tr>
<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1@ 4.83</td>
<td>AF, FM</td>
</tr>
<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1@ 4.83</td>
<td>AF, FM</td>
</tr>
<tr>
<td>5387N</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1@ 3.94</td>
<td>QA</td>
</tr>
<tr>
<td>9148L</td>
<td>lepadinib 250 mg tablet, 70</td>
<td>70@ 1690.52</td>
<td>GK</td>
</tr>
<tr>
<td>8798C</td>
<td>levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 167.75</td>
<td>NV</td>
</tr>
<tr>
<td>9345W</td>
<td>levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 173.77</td>
<td>NV</td>
</tr>
<tr>
<td>8799D</td>
<td>levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 182.77</td>
<td>NV</td>
</tr>
<tr>
<td>9292C</td>
<td>levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 196.60</td>
<td>NV</td>
</tr>
<tr>
<td>8970D</td>
<td>levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags</td>
<td>7@ 1459.49</td>
<td>VE</td>
</tr>
<tr>
<td>8797B</td>
<td>levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 152.73</td>
<td>NV</td>
</tr>
<tr>
<td>9344T</td>
<td>levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 159.35</td>
<td>NV</td>
</tr>
<tr>
<td>8290H</td>
<td>lithium carbonate 450 mg tablet: modified release, 100 tablets</td>
<td>100@ 13.94</td>
<td>AS</td>
</tr>
<tr>
<td>8203R</td>
<td>losartan potassium 50 mg tablet, 30</td>
<td>30@ 8.99</td>
<td>AF</td>
</tr>
<tr>
<td>10112F</td>
<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
<td>1@ 7.88</td>
<td>NE</td>
</tr>
<tr>
<td>10112Y</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>1@ 7.88</td>
<td>NE</td>
</tr>
<tr>
<td>10117B</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>1@ 11.81</td>
<td>AE, GN, HM, NE, QA, TX</td>
</tr>
<tr>
<td>5390Q</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>1@ 11.81</td>
<td>AE, GN, HM, NE, QA, TX</td>
</tr>
<tr>
<td>2351R</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>1@ 11.81</td>
<td>ON</td>
</tr>
<tr>
<td>2353W</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>1@ 11.81</td>
<td>ON</td>
</tr>
<tr>
<td>5426N</td>
<td>mercaptopurine 50 mg tablet: modified release, 100 tablets</td>
<td>1@ 11.81</td>
<td>KY</td>
</tr>
<tr>
<td>5427P</td>
<td>mesalazine 1 g/100 mL enema, 7 x 100 mL</td>
<td>25@ 65.09</td>
<td>AS</td>
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(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

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<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 1.69</td>
<td>BX</td>
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<tr>
<td>5212H</td>
<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
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<td>3199J</td>
<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 7.77</td>
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<td>BN</td>
</tr>
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<td>10242C</td>
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</tr>
<tr>
<td>9380Q</td>
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<td>60@ 3225.33</td>
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<td>2091C</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>1@ 12.93</td>
<td>AE, JT</td>
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<tr>
<td>5332P</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>1@ 12.93</td>
<td>AE, JT</td>
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<tr>
<td>5545W</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>1@ 14.82</td>
<td>RB</td>
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<tr>
<td>944BG</td>
<td>soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can</td>
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<td>8577K</td>
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<td>2093E</td>
<td>sulfasalazine 500 mg tablet, 100</td>
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<td>2090P</td>
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<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
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<td>PF</td>
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<td>8885P</td>
<td>SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2</td>
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<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>30@ 13.96</td>
<td>LN</td>
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<td>temazepam 10 mg tablet, 25</td>
<td>25@ 0.93</td>
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<td>temazepam 10 mg tablet, 25</td>
<td>25@ 4.93</td>
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<td>9160D</td>
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<td>NV</td>
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<td>2822T</td>
<td>tiagabine 15 mg tablet, 50</td>
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<td>50@ 33.10</td>
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<td></td>
<td>1@ 15.70</td>
<td>AS</td>
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<td>tobramycin 80 mg/2 mL injection, 5 x 2 mL vials</td>
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<td>1@ 54.55</td>
<td>VF</td>
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<td>VF</td>
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<td>8478F</td>
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<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>SW</td>
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<td>vancomycin 125 mg capsule, 20</td>
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<td>9382T</td>
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<td>1@ 394.46</td>
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<tr>
<td>8266C</td>
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Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Pharmaceutical Benefits
## Drug Tariff

<table>
<thead>
<tr>
<th>Drug</th>
<th>Standard</th>
<th>Recovery Prices</th>
<th>0.1 g/mL</th>
<th>1 g/mL</th>
<th>10 g/mL</th>
<th>100 g/mL</th>
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<tbody>
<tr>
<td>Acacia Mucilage (by weight)</td>
<td>APF 15</td>
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<td>0.01</td>
<td>0.09</td>
<td>0.70</td>
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<td>0.06</td>
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<td>0.17</td>
<td>1.34</td>
<td>11.88</td>
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<tr>
<td>Cetomacrogol Aqueous Cream</td>
<td>APF</td>
<td></td>
<td>0.01</td>
<td>0.04</td>
<td>0.28</td>
<td>2.51</td>
</tr>
<tr>
<td>Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.02</td>
<td>0.13</td>
<td>1.04</td>
<td>9.22</td>
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<tr>
<td>Chlorhexidine Acetate (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.63</td>
<td>5.02</td>
<td>40.16</td>
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<tr>
<td>Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.03</td>
<td>0.21</td>
<td>1.68</td>
<td>14.96</td>
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<tr>
<td>Chloroform (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.09</td>
<td>0.68</td>
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<td>48.18</td>
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<td>Drug</td>
<td>Standard</td>
<td>Recovery Prices</td>
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<tr>
<td></td>
<td></td>
<td>0.1 g/mL</td>
<td>1 g/mL</td>
<td>10 g/mL</td>
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<tr>
<td>Chloroform Spirit</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.08</td>
<td>$0.64</td>
<td>$5.65</td>
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<tr>
<td>Chloroform Water Concentrated 1 in 40</td>
<td>APF 15</td>
<td>$0.01</td>
<td>$0.10</td>
<td>$0.79</td>
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<td>Citric Acid Monohydrate</td>
<td>BP</td>
<td>$0.03</td>
<td>$0.26</td>
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<td>Coal Tar</td>
<td>BP</td>
<td>$0.23</td>
<td>$1.80</td>
<td>$14.36</td>
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<tr>
<td>Coal Tar Solution</td>
<td>BP</td>
<td>$0.02</td>
<td>$0.13</td>
<td>$1.05</td>
<td>$9.34</td>
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<tr>
<td>Cocaine Hydrochloride</td>
<td>BP</td>
<td>$6.09</td>
<td>$48.74</td>
<td>$389.90</td>
<td>$3465.77</td>
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</tr>
<tr>
<td>Coconut Oil</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.10</td>
<td>$0.80</td>
<td>$7.16</td>
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<tr>
<td>Codeine Linctus</td>
<td>APF</td>
<td>$0.01</td>
<td>$0.06</td>
<td>$0.48</td>
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<tr>
<td>Codeine Phosphate</td>
<td>BP</td>
<td>$2.72</td>
<td>$21.75</td>
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<tr>
<td>Collodion Flexible</td>
<td>BP</td>
<td>$0.18</td>
<td>$1.43</td>
<td>$11.42</td>
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<tr>
<td>Dithranol</td>
<td>BP</td>
<td>$4.77</td>
<td>$38.15</td>
<td>$305.20</td>
<td>$2712.84</td>
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<tr>
<td>Emulsifying Ointment</td>
<td>BP</td>
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<td>$0.06</td>
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<tr>
<td>Ephedrine Hydrochloride</td>
<td>BP</td>
<td>$1.56</td>
<td>$12.49</td>
<td>$99.90</td>
<td>$888.00</td>
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<tr>
<td>Ethanol (90 per cent)</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.03</td>
<td>$0.27</td>
<td>$2.37</td>
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</tr>
<tr>
<td>(use as additive only)</td>
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<td>Ethanol (96 per cent)</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.04</td>
<td>$0.29</td>
<td>$2.54</td>
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<td>(use as additive only)</td>
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<tr>
<td>Ether Solvent</td>
<td>BP</td>
<td>$0.17</td>
<td>$1.34</td>
<td>$10.72</td>
<td>$95.31</td>
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<tr>
<td>(use as additive only)</td>
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<tr>
<td>Eucalyptus Oil</td>
<td>BP</td>
<td>$0.02</td>
<td>$0.14</td>
<td>$1.09</td>
<td>$9.65</td>
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<tr>
<td>(use as additive only)</td>
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<tr>
<td>Ferrous Sulfate</td>
<td>BP</td>
<td>$0.16</td>
<td>$1.28</td>
<td>$10.27</td>
<td>$91.25</td>
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<tr>
<td>Formaldehyde Solution</td>
<td>BP</td>
<td>$0.12</td>
<td>$0.92</td>
<td>$7.37</td>
<td>$65.55</td>
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<tr>
<td>Gentian Alkaline Mixture</td>
<td>APF</td>
<td>$0.01</td>
<td>$0.07</td>
<td>$0.52</td>
<td>$4.63</td>
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<tr>
<td>Glycerol</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.07</td>
<td>$0.59</td>
<td>$5.23</td>
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<tr>
<td>Honey Purified</td>
<td>BP 1993</td>
<td>$0.01</td>
<td>$0.02</td>
<td>$0.17</td>
<td>$1.53</td>
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<tr>
<td>(use as additive only)</td>
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<td></td>
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<tr>
<td>Hydroxybenzoate Compound Solution</td>
<td>APF</td>
<td>$0.07</td>
<td>$0.59</td>
<td>$4.72</td>
<td>$41.96</td>
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<tr>
<td>Iodine</td>
<td>BP</td>
<td>$0.27</td>
<td>$2.18</td>
<td>$17.40</td>
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<tr>
<td>Iodine Alcoholic Solution</td>
<td>BP</td>
<td>$0.03</td>
<td>$0.21</td>
<td>$1.69</td>
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<tr>
<td>Iodine Aqueous Oral Solution</td>
<td>BP</td>
<td>$0.04</td>
<td>$0.29</td>
<td>$2.35</td>
<td>$20.88</td>
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<tr>
<td>Kaolin Mixture</td>
<td>BPC 1968</td>
<td>$0.01</td>
<td>$0.10</td>
<td>$0.83</td>
<td>$7.37</td>
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<tr>
<td>Kaolin and Opium Mixture</td>
<td>APF 14</td>
<td>$0.01</td>
<td>$0.09</td>
<td>$0.69</td>
<td>$6.10</td>
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<tr>
<td>Lactic Acid</td>
<td>BP</td>
<td>$0.08</td>
<td>$0.64</td>
<td>$5.09</td>
<td>$45.21</td>
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<tr>
<td>Lavender Spike Oil</td>
<td>BPC 1968</td>
<td>$0.11</td>
<td>$0.87</td>
<td>$6.95</td>
<td>$61.75</td>
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<tr>
<td>Liquorice Liquid Extract</td>
<td>BP</td>
<td>$0.03</td>
<td>$0.25</td>
<td>$1.99</td>
<td>$17.70</td>
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<tr>
<td>Magnesium Carbonate Light</td>
<td>BP</td>
<td>$0.04</td>
<td>$0.34</td>
<td>$2.74</td>
<td>$24.38</td>
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<tr>
<td>Magnesium Sulfate</td>
<td>BP</td>
<td>$0.01</td>
<td>$0.01</td>
<td>$0.11</td>
<td>$0.98</td>
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</tr>
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<td></td>
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<td></td>
</tr>
<tr>
<td>(may only be prescribed for other than oral use)</td>
<td></td>
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</tr>
<tr>
<td>Drug</td>
<td>Standard</td>
<td>0.1 g/mL</td>
<td>1 g/mL</td>
<td>10 g/mL</td>
<td>100 g/mL</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
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<tr>
<td>Magnesium Trisilicate</td>
<td>BP</td>
<td>0.04</td>
<td>0.34</td>
<td>2.69</td>
<td>23.95</td>
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<tr>
<td>Menthol, Racemic or Levomenthol</td>
<td>BP</td>
<td>0.26</td>
<td>2.11</td>
<td>16.87</td>
<td>149.94</td>
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<tr>
<td>Methyl Hydroxybenzoate</td>
<td>BP</td>
<td>0.36</td>
<td>2.87</td>
<td>22.94</td>
<td>203.91</td>
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<tr>
<td>Methyl Hydroxybenzoate Solution</td>
<td>APF</td>
<td>0.04</td>
<td>0.30</td>
<td>2.41</td>
<td>21.43</td>
<td></td>
</tr>
<tr>
<td>Methylated Industrial Spirit</td>
<td>BP</td>
<td>0.01</td>
<td>0.04</td>
<td>0.30</td>
<td>2.67</td>
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<tr>
<td>Olive Oil</td>
<td>BP</td>
<td>0.01</td>
<td>0.10</td>
<td>0.78</td>
<td>6.93</td>
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</tr>
<tr>
<td>Paraffin Hard</td>
<td>BP</td>
<td>0.04</td>
<td>0.28</td>
<td>2.22</td>
<td>19.76</td>
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</tr>
<tr>
<td>Paraffin Liquid</td>
<td>BP</td>
<td>0.01</td>
<td>0.03</td>
<td>0.26</td>
<td>2.35</td>
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</tr>
<tr>
<td>Paraffin Light Liquid</td>
<td>BP</td>
<td>0.02</td>
<td>0.17</td>
<td>1.39</td>
<td>12.38</td>
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<tr>
<td>Paraffin Soft White</td>
<td>BP</td>
<td>0.01</td>
<td>0.04</td>
<td>0.35</td>
<td>3.12</td>
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</tr>
<tr>
<td>Paraffin Soft Yellow</td>
<td>BP</td>
<td>0.01</td>
<td>0.04</td>
<td>0.35</td>
<td>3.12</td>
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<tr>
<td>Peppermint Oil</td>
<td>BP</td>
<td>0.14</td>
<td>1.14</td>
<td>9.14</td>
<td>81.21</td>
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<tr>
<td>Peppermint Water Concentrated 1 in 40</td>
<td>APF 16</td>
<td>0.04</td>
<td>0.31</td>
<td>2.51</td>
<td>22.35</td>
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<tr>
<td>Phenobarbitone Sodium</td>
<td>BP</td>
<td>10.67</td>
<td>85.38</td>
<td>683.00</td>
<td>6071.11</td>
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<tr>
<td>Phenol Liquefied</td>
<td>BP</td>
<td>0.20</td>
<td>1.58</td>
<td>12.67</td>
<td>112.59</td>
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<tr>
<td>Podophyllum Resin</td>
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<td>3.50</td>
<td>27.99</td>
<td>223.88</td>
<td>1990.04</td>
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<tr>
<td>Potassium Citrate</td>
<td>BP</td>
<td>0.02</td>
<td>0.18</td>
<td>1.40</td>
<td>12.41</td>
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<tr>
<td>Potassium Iodide</td>
<td>BP</td>
<td>0.11</td>
<td>0.84</td>
<td>6.73</td>
<td>59.80</td>
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<tr>
<td>Potassium Permanganate</td>
<td>BP</td>
<td>0.04</td>
<td>0.32</td>
<td>2.58</td>
<td>22.96</td>
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<tr>
<td>Propyl Hydroxybenzoate</td>
<td>BP</td>
<td>0.28</td>
<td>2.25</td>
<td>17.98</td>
<td>159.82</td>
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<tr>
<td>Propylene Glycol</td>
<td>BP</td>
<td>0.01</td>
<td>0.10</td>
<td>0.80</td>
<td>7.09</td>
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<tr>
<td>Red Syrup</td>
<td>APF 15</td>
<td>0.02</td>
<td>0.13</td>
<td>1.07</td>
<td>9.50</td>
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</tr>
<tr>
<td>Resorcinol</td>
<td>BP</td>
<td>0.37</td>
<td>2.97</td>
<td>23.76</td>
<td>211.20</td>
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<tr>
<td>Salicylic Acid</td>
<td>BP</td>
<td>0.04</td>
<td>0.29</td>
<td>2.28</td>
<td>20.24</td>
<td></td>
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<tr>
<td>Salicylic Acid Ointment</td>
<td>APF</td>
<td>0.02</td>
<td>0.13</td>
<td>1.01</td>
<td>9.00</td>
<td></td>
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<tr>
<td>Salicylic Acid Ointment</td>
<td>BP</td>
<td>0.02</td>
<td>0.13</td>
<td>1.01</td>
<td>9.00</td>
<td></td>
</tr>
<tr>
<td>Simple Ointment (white)</td>
<td>BP</td>
<td>0.02</td>
<td>0.15</td>
<td>1.16</td>
<td>10.33</td>
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<tr>
<td>Simple Ointment (yellow)</td>
<td>BP</td>
<td>0.02</td>
<td>0.15</td>
<td>1.16</td>
<td>10.33</td>
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<tr>
<td>Sodium Bicarbonate</td>
<td>BP</td>
<td>0.01</td>
<td>0.09</td>
<td>0.75</td>
<td>6.67</td>
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<tr>
<td>Sodium Chloride</td>
<td>BP</td>
<td>0.02</td>
<td>0.15</td>
<td>1.20</td>
<td>10.64</td>
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<tr>
<td>Sodium Chloride Solution</td>
<td>BP</td>
<td>0.01</td>
<td>0.01</td>
<td>0.08</td>
<td>0.73</td>
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</tr>
<tr>
<td>Sodium Citrate</td>
<td>BP</td>
<td>0.03</td>
<td>0.25</td>
<td>1.97</td>
<td>17.48</td>
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</tr>
<tr>
<td>Drug</td>
<td>Standard</td>
<td>Recovery Prices</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>------------------------------------------</td>
<td>------------------------</td>
<td>-----------------</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>0.1 g/mL</td>
<td>1 g/mL</td>
<td>10 g/mL</td>
<td>100 g/mL</td>
<td></td>
</tr>
<tr>
<td>Sodium Thiosulfate (use as additive only)</td>
<td>BP</td>
<td></td>
<td>$0.03</td>
<td>$0.24</td>
<td>$1.95</td>
<td>$17.35</td>
</tr>
<tr>
<td>Starch</td>
<td>BP</td>
<td></td>
<td>$0.02</td>
<td>$0.16</td>
<td>$1.27</td>
<td>$11.27</td>
</tr>
<tr>
<td>Sulfur Ointment (for use only as a base combined with active ingredients)</td>
<td>BP 1980</td>
<td></td>
<td>$0.02</td>
<td>$0.15</td>
<td>$1.20</td>
<td>$10.66</td>
</tr>
<tr>
<td>Sulfur Precipitated</td>
<td>BP 1980</td>
<td></td>
<td>$0.02</td>
<td>$0.17</td>
<td>$1.35</td>
<td>$12.04</td>
</tr>
<tr>
<td>Syrup</td>
<td>BP</td>
<td></td>
<td>$0.01</td>
<td>$0.03</td>
<td>$0.23</td>
<td>$2.07</td>
</tr>
<tr>
<td>Talc Purified, sterilised</td>
<td>BP</td>
<td></td>
<td>$0.03</td>
<td>$0.27</td>
<td>$2.12</td>
<td>$18.84</td>
</tr>
<tr>
<td>Thymol</td>
<td>BP</td>
<td></td>
<td>$0.25</td>
<td>$2.03</td>
<td>$16.24</td>
<td>$144.36</td>
</tr>
<tr>
<td>Thymol Compound Mouth Wash</td>
<td>APF 15</td>
<td></td>
<td>$0.01</td>
<td>$0.10</td>
<td>$0.81</td>
<td>$7.22</td>
</tr>
<tr>
<td>Tragacanth Compound Powder</td>
<td>BP 1980</td>
<td></td>
<td>$0.08</td>
<td>$0.60</td>
<td>$4.76</td>
<td>$42.31</td>
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<tr>
<td>Tragacanth Mucilage</td>
<td>APF 13</td>
<td></td>
<td>$0.01</td>
<td>$0.06</td>
<td>$0.44</td>
<td>$3.90</td>
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<tr>
<td>Tragacanth Mucilage</td>
<td>BPC 1973</td>
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<td>$0.01</td>
<td>$0.05</td>
<td>$0.37</td>
<td>$3.32</td>
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<tr>
<td>Tragacanth, powdered</td>
<td>BP</td>
<td></td>
<td>$0.25</td>
<td>$1.96</td>
<td>$15.64</td>
<td>$139.05</td>
</tr>
<tr>
<td>Trichloroacetic Acid</td>
<td>BP 1980</td>
<td></td>
<td>$0.35</td>
<td>$2.83</td>
<td>$22.63</td>
<td>$201.12</td>
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<tr>
<td>Triethanolamine</td>
<td>BP</td>
<td></td>
<td>$0.06</td>
<td>$0.51</td>
<td>$4.08</td>
<td>$36.25</td>
</tr>
<tr>
<td>Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)</td>
<td>BP</td>
<td></td>
<td>—</td>
<td>—</td>
<td>$11.37</td>
<td>$11.37</td>
</tr>
<tr>
<td>Water Purified</td>
<td>BP</td>
<td></td>
<td>$0.01</td>
<td>$0.01</td>
<td>$0.07</td>
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<tr>
<td>Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)</td>
<td>BP</td>
<td></td>
<td>$0.02</td>
<td>$0.15</td>
<td>$1.16</td>
<td>$10.34</td>
</tr>
<tr>
<td>Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)</td>
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<td></td>
<td>$0.02</td>
<td>$0.15</td>
<td>$1.16</td>
<td>$10.34</td>
</tr>
<tr>
<td>Wool Fat</td>
<td>BP</td>
<td></td>
<td>$0.02</td>
<td>$0.14</td>
<td>$1.08</td>
<td>$9.58</td>
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<td>Wool Fat Hydrous</td>
<td>BP</td>
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<td>$0.02</td>
<td>$0.13</td>
<td>$1.05</td>
<td>$9.36</td>
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<tr>
<td>Zinc Compound Paste</td>
<td>BP</td>
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<td>$0.04</td>
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<tr>
<td>Zinc Cream (for use only as a base combined with active ingredients)</td>
<td>BP</td>
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<td>$0.01</td>
<td>$0.08</td>
<td>$0.62</td>
<td>$5.49</td>
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<td>Zinc Oxide</td>
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<td>$0.02</td>
<td>$0.15</td>
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<td>$10.81</td>
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<td>Zinc and Salicylic Acid Paste</td>
<td>BP</td>
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<td>$0.02</td>
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<td>Zinc Sulfate</td>
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<td>$0.03</td>
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## Container Prices

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Size</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DISPENSING BOTTLES –</strong></td>
<td>25mL</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td>50mL</td>
<td>0.58</td>
</tr>
<tr>
<td></td>
<td>100mL</td>
<td>0.76</td>
</tr>
<tr>
<td></td>
<td>200mL</td>
<td>0.98</td>
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<tr>
<td></td>
<td>500mL</td>
<td>1.34</td>
</tr>
<tr>
<td><strong>POISON BOTTLES –</strong></td>
<td>25mL</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>50mL</td>
<td>0.74</td>
</tr>
<tr>
<td></td>
<td>100mL</td>
<td>0.77</td>
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<tr>
<td></td>
<td>200mL</td>
<td>1.14</td>
</tr>
<tr>
<td></td>
<td>500mL</td>
<td>1.34</td>
</tr>
<tr>
<td><strong>SCREW CAP JARS –</strong></td>
<td>25g</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>50g</td>
<td>1.09</td>
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<td></td>
<td>100g</td>
<td>1.25</td>
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<td></td>
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<td>0.89</td>
</tr>
<tr>
<td></td>
<td>500g</td>
<td>1.29</td>
</tr>
<tr>
<td><strong>DROPPER CONTAINERS –</strong></td>
<td>15mL polythene</td>
<td>0.89</td>
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<tr>
<td></td>
<td>15mL glass</td>
<td>0.86</td>
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**Dispensing Fee for Extemporaneously Prepared Benefits** 8.80

**Additional Fee for Agreed Price Extemporaneously Prepared Benefits** 1.50
**Standard Formula Preparations**

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

**KEY TO REFERENCES:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Item</th>
<th>Reference</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CREAMS (Maximum Quantity 100 g and 1 Repeat)</td>
<td></td>
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<td></td>
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<tr>
<td>7502W</td>
<td>Salicylic Acid and Sulfur Aqueous</td>
<td>APF</td>
<td>12.55</td>
<td>14.05</td>
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<tr>
<td></td>
<td>DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)</td>
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<td></td>
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<tr>
<td>7458M</td>
<td>Zinc, Starch and Talc</td>
<td>APF 15 &amp; BPC 1973</td>
<td>26.50</td>
<td>28.00</td>
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<td></td>
<td>EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)</td>
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<td></td>
<td></td>
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<tr>
<td>7642F</td>
<td>Aluminium Acetate</td>
<td>APF</td>
<td>10.91</td>
<td>12.41</td>
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<tr>
<td>7643G</td>
<td>Aluminium Acetate</td>
<td>BP</td>
<td>11.63</td>
<td>13.13</td>
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<tr>
<td>7314Y</td>
<td>Sodium Bicarbonate</td>
<td>APF &amp; BP</td>
<td>10.16</td>
<td>11.66</td>
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<tr>
<td>7313X</td>
<td>Spirit</td>
<td>APF</td>
<td>9.94</td>
<td>11.44</td>
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<tr>
<td></td>
<td>INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)</td>
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<td></td>
<td></td>
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<tr>
<td>7484X</td>
<td>Benzoin and Menthol</td>
<td>APF</td>
<td>21.44</td>
<td>22.94</td>
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<tr>
<td>7308P</td>
<td>Menthol</td>
<td>APF</td>
<td>12.99</td>
<td>14.49</td>
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<tr>
<td>7310R</td>
<td>Menthol and Eucalyptus</td>
<td>BP 1980</td>
<td>13.83</td>
<td>15.33</td>
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<td></td>
<td>LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and 0 Repeats)</td>
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<tr>
<td>7530H</td>
<td>Codeine</td>
<td>APF</td>
<td>13.82</td>
<td>15.32</td>
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<td></td>
<td>LOTIONS (Maximum Quantity 200 mL and 2 Repeats)</td>
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<td></td>
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<tr>
<td>7709R</td>
<td>Aluminium Acetate Aqueous</td>
<td>APF</td>
<td>12.35</td>
<td>13.85</td>
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<td></td>
<td>MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)</td>
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<td></td>
<td></td>
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<tr>
<td>7604F</td>
<td>Gentian Alkaline</td>
<td>APF</td>
<td>19.05</td>
<td>20.55</td>
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<tr>
<td>7348R</td>
<td>Kaolin</td>
<td>BPC 1968</td>
<td>24.52</td>
<td>26.02</td>
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<tr>
<td>7301G</td>
<td>Kaolin and Opium</td>
<td>APF 14</td>
<td>21.97</td>
<td>23.47</td>
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<tr>
<td>7342K</td>
<td>Magnesium Trisilicate</td>
<td>BPC 1968</td>
<td>18.68</td>
<td>20.18</td>
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<tr>
<td>7343L</td>
<td>Magnesium Trisilicate and Belladonna</td>
<td>BPC 1968</td>
<td>24.26</td>
<td>25.76</td>
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<tr>
<td>Code</td>
<td>Item</td>
<td>Reference</td>
<td>Dispensed Price for Max. Qty</td>
<td>Maximum Recordable Value for Safety Net</td>
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<td>------</td>
<td>------</td>
<td>-----------</td>
<td>-----------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>7457L</td>
<td>Thymol Compound</td>
<td>APF 15</td>
<td>24.39</td>
<td>25.89</td>
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<tr>
<td>7914M</td>
<td>Benzoic Acid Compound</td>
<td>APF &amp; BP</td>
<td>18.86</td>
<td>20.36</td>
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<tr>
<td>7902X</td>
<td>Boric Acid, Olive Oil and Zinc Oxide</td>
<td>QHF</td>
<td>16.94</td>
<td>18.44</td>
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<tr>
<td>7926E</td>
<td>Salicylic Acid</td>
<td>APF</td>
<td>19.05</td>
<td>20.55</td>
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<tr>
<td>7928G</td>
<td>Salicylic Acid (extemporaneous formula)</td>
<td>BP</td>
<td>19.05</td>
<td>20.55</td>
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<tr>
<td>7567G</td>
<td>Podophyllin Compound</td>
<td>APF 16 &amp; BP</td>
<td>119.29</td>
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<td>7568H</td>
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<td>38.72</td>
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<td>Zinc</td>
<td>APF &amp; BP</td>
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<td>7545D</td>
<td>Magnesium Trisilicate</td>
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---CONTAINER RATES ARE INCLUDED---
### Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

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<thead>
<tr>
<th>Code</th>
<th>Preparation</th>
<th>Maximum Quantity</th>
<th>Number of Repeats</th>
</tr>
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<tbody>
<tr>
<td>13Q</td>
<td>Creams</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>48M</td>
<td>Dusting Powders</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>15T</td>
<td>Ear Drops</td>
<td>15 mL</td>
<td>2</td>
</tr>
<tr>
<td>19B</td>
<td>Eye Drops containing Cocaine Hydrochloride</td>
<td>15 mL</td>
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</tr>
<tr>
<td>22E</td>
<td>Eye Drops, Other</td>
<td>15 mL</td>
<td>5</td>
</tr>
<tr>
<td>23F</td>
<td>Eye Lotions</td>
<td>200 mL</td>
<td>2</td>
</tr>
<tr>
<td>29M</td>
<td>Inhalations</td>
<td>50 mL</td>
<td>1</td>
</tr>
<tr>
<td>64J</td>
<td>Linctuses containing Codeine Phosphate</td>
<td>100 mL</td>
<td>..</td>
</tr>
<tr>
<td>34T</td>
<td>Linctuses, Other</td>
<td>100 mL</td>
<td>2</td>
</tr>
<tr>
<td>39C</td>
<td>Lotions</td>
<td>200 mL</td>
<td>2</td>
</tr>
<tr>
<td>65K</td>
<td>Mixtures containing Codeine Phosphate</td>
<td>200 mL</td>
<td>..</td>
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<tr>
<td>40D</td>
<td>Mixtures, Other</td>
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<td>4</td>
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<tr>
<td>66L</td>
<td>Mixtures for Children containing Codeine Phosphate</td>
<td>100 mL</td>
<td>..</td>
</tr>
<tr>
<td>41E</td>
<td>Mixtures for Children, Other</td>
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<td>4</td>
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<td>30N</td>
<td>Mouth Washes</td>
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<tr>
<td>42F</td>
<td>Nasal Instillations</td>
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<td>2</td>
</tr>
<tr>
<td>43G</td>
<td>Ointments, Waxes</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>44H</td>
<td>Paints</td>
<td>25 mL</td>
<td>1</td>
</tr>
<tr>
<td>63H</td>
<td>Pastes containing Cocaine Hydrochloride</td>
<td>25 g</td>
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<tr>
<td>45J</td>
<td>Pastes, Other</td>
<td>100 g</td>
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<td>49N</td>
<td>Powders for Internal Use</td>
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<tr>
<td>52R</td>
<td>Solutions</td>
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<td>2</td>
</tr>
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</table>

Special Note: Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.
The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);
BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

**Gold card**
This card is issued to those veterans of Australia’s defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

**White card**
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

**Orange card**
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans' Affairs website:
RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.

- Through the Veterans’ Entitlements Act 1986 the Department of Veterans’ Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the Schedule of Pharmaceutical Benefits book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient’s full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the National Health Act 1953; and
  - other items not listed in either Schedule (non-Schedule items).

- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the Schedule of Pharmaceutical Benefits (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)

- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department’s national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient’s condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.

Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.

For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.

Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.

A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. The Department of Human Services will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans’ Affairs for payment.

**Palliative Care Drugs**

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine
  - dexamethasone
  - disodium pamidronate
  - fentanyl
  - glycopyrrolate
  - hyoscine butylbromide
  - hyoscine hydrobromide
  - ketamine
  - midazolam
  - octreotide

For further information telephone VAPAC on 1800 552 580.

**Dental Prescribing**

- Under Department of Veterans’ Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.

- Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).

- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.

- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO’s private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

**Prescribing by optometrists**

- Optometrists approved as ‘PBS prescribers’ may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.

- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe ‘Authority required’ optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).

Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.

- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the Schedule of Pharmaceutical Benefits.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.

- If multiple quantities of a manufacturer’s original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer’s original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.

- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.

- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.

- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.
Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patient's name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. The Department of Human Services will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from the Department of Human Services. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words “This prescription does not attract a therapeutic group premium”.

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans’ Affairs Pharmaceutical Advisory Centre)
Department of Veterans’ Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.
SUMMARY OF CHANGES

There is NO changes in Repatriation Schedule of Pharmaceutical Benefits for this month.
# Therapeutic Index for RPBS

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## Blood and Blood Forming Organs

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<td>Blood Substitutes and Perfusion Solutions</td>
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<td>Irrigating Solutions</td>
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## Cardiovascular System

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<td>Agents for Treatment of Hemorrhoids and Anal Fissures for Topical Use</td>
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## Dermatologicals

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<td>Emollients and Protective Agents</td>
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<td>Antipruritics, Incl. Antihistamines, Anesthetics, Etc.</td>
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<tr>
<td>Antipruritics, Incl. Antihistamines, Anesthetics, Etc.</td>
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<td>Antipsoriatrics</td>
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<td>Chemotherapeutics for Topical Use</td>
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<td>Corticosteroids, Dermatological Preparations</td>
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<td>Corticosteroids, Plain</td>
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<td>Antiseptics and Disinfectants</td>
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<td>Antiseptics and Disinfectants</td>
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<td>Other Dermatological Preparations</td>
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<tr>
<td>Other Dermatological Preparations</td>
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## Genito Urinary System and Sex Hormones

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<td>Other Gynecologicals</td>
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<td>Urologicals</td>
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<td>Urologicals</td>
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<td>Drugs Used in Benign Prostatic Hypertrophy</td>
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## Antiinfectives for Systemic Use

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<td>Antibacterials for Systemic Use</td>
<td>1254</td>
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Section 1

Drugs, Medicines and Dressings
## ALIMENTARY TRACT AND METABOLISM

### STOMATOLOGICAL PREPARATIONS

#### Antiinfectives and antiseptics for local oral treatment

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4161B</td>
<td>Chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 250 mL</td>
<td>12.23</td>
<td>6.10</td>
<td>6.10</td>
<td>Plaqacide OB</td>
</tr>
<tr>
<td>4204G</td>
<td>Chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 300 mL</td>
<td>15.62</td>
<td>6.10</td>
<td>6.10</td>
<td>Savacol Mouth and Throat Rinse OM</td>
</tr>
</tbody>
</table>

### DRUGS FOR ACID RELATED DISORDERS

#### ANTACIDS

**Calcium compounds**

- **CALCIUM CARBONATE + GLYCINE**
  
  **Note**
  For patients with chronic renal failure.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4055K</td>
<td>Calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100</td>
<td>23.52</td>
<td>6.10</td>
<td>6.10</td>
<td>Titalac MM</td>
</tr>
</tbody>
</table>

#### Combinations and complexes of aluminium, calcium and magnesium compounds

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4118R</td>
<td>Aluminium hydroxide with magnesium hydroxide and simethicone</td>
<td>22.98</td>
<td>6.10</td>
<td>6.10</td>
<td>Mylanta Double Strength JT</td>
</tr>
<tr>
<td>4453J</td>
<td>Aluminium hydroxide with magnesium hydroxide and simethicone Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1</td>
<td>46.46</td>
<td>6.10</td>
<td>6.10</td>
<td>Mylanta Double Strength JT</td>
</tr>
<tr>
<td>4118R</td>
<td>Aluminium hydroxide with magnesium hydroxide and simethicone Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1</td>
<td>46.46</td>
<td>6.10</td>
<td>6.10</td>
<td>Mylanta Double Strength JT</td>
</tr>
</tbody>
</table>

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

#### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

**Synthetic anticholinergics, esters with tertiary amino group**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4328T</td>
<td>Mebeverine hydrochloride 135 mg tablet, 90</td>
<td>27.25</td>
<td>6.10</td>
<td>6.10</td>
<td>a Colese AF</td>
</tr>
<tr>
<td>4279F</td>
<td>Hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
<td>24.55</td>
<td>6.10</td>
<td>6.10</td>
<td>Buscopan BY</td>
</tr>
</tbody>
</table>

### DRUGS FOR CONSTIPATION

#### Softeners, emollients

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4200C</td>
<td>Docusate sodium 50 mg tablet, 100</td>
<td>14.65</td>
<td>6.10</td>
<td>6.10</td>
<td>Coloxyl 50 FM</td>
</tr>
</tbody>
</table>

#### Contact laxatives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4028B</td>
<td>Docusate sodium 50 mg + sennoside B 8 mg tablet, 100</td>
<td>14.75</td>
<td>6.10</td>
<td>6.10</td>
<td>Soflax GN</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Premium $ for Max. Qty</td>
<td>Maximum Recordable Value for Safety Net $</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------</td>
<td>------------------</td>
<td>-------------</td>
<td>------------------------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>10177P</td>
<td>docusate sodium 50 mg + sennoside B 8 mg tablet, 90</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.48</td>
</tr>
<tr>
<td>4198Y</td>
<td>docusate sodium 50 mg + sennosides 11.27 mg tablet, 90</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>17.03</td>
</tr>
<tr>
<td>4455L</td>
<td>sennoside B 7.5 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>12.94</td>
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</tbody>
</table>

**Bulk-forming laxatives**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4285M</td>
<td>ispaghula husk dry 3.5 g oral liquid: powder for, 30 x 3.5 g sachets</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>17.98</td>
<td>Fybogel RC</td>
</tr>
<tr>
<td>4422R</td>
<td>psyllium hydrophilic mucilloid oral powder (non-flavoured) 336 g, 1</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>18.36</td>
<td>Fibre Health Natural PP</td>
</tr>
<tr>
<td>4419N</td>
<td>psyllium hydrophilic mucilloid oral powder (orange-flavoured, sugar-free) 283 g, 1</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>22.01</td>
<td>Metamucil Granular PY</td>
</tr>
<tr>
<td>4558X</td>
<td>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>26.71</td>
<td>Normacol Plus NE</td>
</tr>
</tbody>
</table>

**Enemas**

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<th>Code</th>
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<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4462W</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.44</td>
<td>Micolette AE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Microlax JT</td>
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</table>

**Other drugs for constipation**

<table>
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<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4246L</td>
<td>glycerol 2.8 g suppository</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*22.15</td>
<td>Petrus Pharmaceuticals PP Ltd</td>
</tr>
</tbody>
</table>

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

**Peripheral acting antiobesity products**

<table>
<thead>
<tr>
<th>CODE</th>
<th>Name</th>
<th>Authority required</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORL</td>
<td>Authority required</td>
<td></td>
<td>For the treatment of obese patients.</td>
</tr>
<tr>
<td></td>
<td>Total treatment will not exceed 12 months from initial application.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients are eligible for 1 continuous treatment in a lifetime.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial treatment for patients who meet the following criteria to qualify:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(i) diabetes;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(ii) ischaemic heart disease;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(iii) psychiatric conditions;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(iv) hypertension.

The prescriber must provide the following:
(a) initial body weight; and
(b) BMI.

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient’s initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser).

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient’s initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser).

Note
The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4570M</td>
<td>orlistat 120 mg capsule, 84</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>140.50</td>
<td>6.10</td>
<td>Xenical RO</td>
</tr>
</tbody>
</table>

**VITAMINS**

**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12**

*Vitamin B1, plain*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4043T</td>
<td>thiamine hydrochloride 100 mg tablet, 100</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>10.45</td>
<td>6.10</td>
<td>Betavit PP</td>
</tr>
</tbody>
</table>

**VITAMIN B-COMPLEX, INCL. COMBINATIONS**

*Vitamin B-complex, plain*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4493L</td>
<td>cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>13.68</td>
<td>6.10</td>
<td>Accomin Adult Tonic PF</td>
</tr>
</tbody>
</table>

**MINERAL SUPPLEMENTS**

**CALCIUM**

*Calcium*

**CALCIUM**

*Restricted benefit*

Hyperphosphataemia in chronic renal failure

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4094L</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>4</td>
<td>1</td>
<td>...</td>
<td>*29.24</td>
<td>6.10</td>
<td>Cal-500 PP</td>
</tr>
<tr>
<td>4142B</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
<td>2</td>
<td>1</td>
<td>...</td>
<td>*22.54</td>
<td>6.10</td>
<td>Cal-Sup IA</td>
</tr>
</tbody>
</table>

**CALCIUM**

*Restricted benefit*

Hypocalcaemia

*Restricted benefit*

Osteoporosis

*Restricted benefit*

Proven calcium malabsorption

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4333C</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>2</td>
<td>1</td>
<td>...</td>
<td>*18.00</td>
<td>6.10</td>
<td>Cal-500 PP</td>
</tr>
<tr>
<td>4082W</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
<td>1</td>
<td>1</td>
<td>...</td>
<td>14.65</td>
<td>6.10</td>
<td>Cal-Sup IA</td>
</tr>
</tbody>
</table>

**OTHER MINERAL SUPPLEMENTS**

*Magnesium*

**MAGNESIUM ASPARTATE DIHYDRATE**
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| 4321K | Restricted benefit  
Patients with documented hypomagnesaemia  
magnesium aspartate dihydrate 500 mg  
(equivalent to 37.4 mg of magnesium) tablet, 50 | 1 | . | 14.04 | 6.10 | Mag-Sup | PP |
|      |                                                   | . |   | 14.73 | 6.10 | Magmin | BB |
### BLOOD AND BLOOD FORMING ORGANS

#### ANTITHROMBOTIC AGENTS

**Platelet aggregation inhibitors excl. heparin**

**ASPIRIN**

**Note**
The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Description</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Safety Net Value for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4078P</td>
<td>aspirin 100 mg capsule: enteric, 84</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>14.96</td>
<td>6.10</td>
<td>Astrix YN</td>
</tr>
<tr>
<td>4077N</td>
<td>aspirin 100 mg tablet: enteric, 84</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>14.05</td>
<td>6.10</td>
<td>Cartia AS a Pharmacy Action Low Dose Aspirin GQ</td>
</tr>
</tbody>
</table>

**CLOPIDOGREL**

**Authority required**

For use in patients pre- and post-angioplasty

**Note**
Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Description</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Safety Net Value for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10169F</td>
<td>clopidogrel 75 mg tablet, 28</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.70</td>
<td>6.10</td>
<td>Clopidogrel GH GQ</td>
</tr>
<tr>
<td>4179Y</td>
<td>clopidogrel 75 mg tablet, 28</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.70</td>
<td>6.10</td>
<td>APO-Clopidogrel TX a Chem mart Clopidogrel CH a Iscover AV a Plax AF a Plavix SW a Piax AF a Plavix SW a Terry White Chemists Clopidogrel TW</td>
</tr>
</tbody>
</table>

#### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

**IRRIGATING SOLUTIONS**

**Salt solutions**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Description</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Safety Net Value for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4460R</td>
<td>sodium chloride 0.9% (4.5 g/500 mL) solution, 1 x 500 mL bottle</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>10.67</td>
<td>6.10</td>
<td>Baxter Healthcare Pty Ltd BX</td>
</tr>
<tr>
<td>4461T</td>
<td>sodium chloride 0.9% (9 g/1000 mL) solution, 1 x 1000 mL bottle</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>10.99</td>
<td>6.10</td>
<td>Baxter Healthcare Pty Ltd BX</td>
</tr>
</tbody>
</table>
### CARDIOVASCULAR SYSTEM

#### VASOPROTECTIVES

**Agents for Treatment of Hemorrhoids and Anal Fissures for Topical Use**  
*Other agents for treatment of hemorrhoids and anal fissures for topical use*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4039N</td>
<td>Zinc oxide + Peru Balsam + Benzyl Benzoate</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.78</td>
<td>6.10</td>
<td>Anusol JT</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide 10.75% (107.5 mg/g) + peru balsam 1.88% (18.8 mg/g) + benzyl benzoate 1.25% (12.5 mg/g) ointment. 50 g</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4040P</td>
<td>Zinc oxide + Peru Balsam + Benzyl Benzoate</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>13.69</td>
<td>6.10</td>
<td>Anusol JT</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository. 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
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<td>No. of Rpts</td>
<td>Dispensed Price for Max. Qty $</td>
<td>Premium $</td>
<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>-------</td>
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<td>---------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>4001N</td>
<td>Nystatin 100 000 international units/g cream, 15 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>12.83</td>
<td>6.10</td>
<td>Mycostatin FM</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4004R</td>
<td>Clotrimazole 1% (10 mg/g) cream, 20 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>8.78</td>
<td>6.10 a</td>
<td>Pharmacy Action Anti-Fungal Cream GQ a</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Clonea AF</td>
</tr>
<tr>
<td>4007X</td>
<td>Ketoconazole 2% (20 mg/g) shampoo, 100 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>19.71</td>
<td>6.10</td>
<td>Sebizole GN</td>
</tr>
<tr>
<td>4008Y</td>
<td>Ketoconazole 2% (20 mg/g) shampoo, 60 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>18.65</td>
<td>6.10</td>
<td>Nizoral 2% JT</td>
</tr>
<tr>
<td>4341L</td>
<td>Miconazole 2% solution, 30 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>19.81</td>
<td>6.10</td>
<td>Daktarin Tincture JT</td>
</tr>
<tr>
<td>4454K</td>
<td>Miconazole nitrate 2% (20 mg/g) cream, 30 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.13</td>
<td>6.10</td>
<td>Daktarin JT</td>
</tr>
<tr>
<td>3400Y</td>
<td>Miconazole nitrate 2% (20 mg/g) cream, 40 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.02</td>
<td>6.10</td>
<td>Resolve Thrush EO</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4010C</td>
<td>Amorolfine 5% application, 5 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>86.85</td>
<td>6.10</td>
<td>Aporyl TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4106D</td>
<td>Ciclopirox olamine 1.5% (15 mg/g) shampoo, 60 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>19.08</td>
<td>6.10</td>
<td>Stieprox Liquid GK</td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>4463K</td>
<td>Terbinafine 1% gel, 15 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>23.69</td>
<td>6.10</td>
<td>Lamisil DermGel NC</td>
</tr>
<tr>
<td>4473K</td>
<td>Terbinafine hydrochloride 1% cream, 15 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>22.23</td>
<td>6.10</td>
<td>Lamisil NC</td>
</tr>
<tr>
<td>4481W</td>
<td>Tolnaftate 0.07% (700 microgram/g) spray, 100 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>15.43</td>
<td>6.10</td>
<td>Tinaderm BN</td>
</tr>
</tbody>
</table>
## DERMATOLOGICALS

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4011D</td>
<td>terbinafine 250 mg tablet, 42</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>38.82</td>
<td>6.10</td>
<td>a GenRx Terbinafine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Lamisil (Novartis Pharmaceuticals Australia Pty Limited)</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>a Tamsil</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Terbinafine GH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Terbinafine Sandoz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Tinasil</td>
</tr>
</tbody>
</table>

### Authority required

Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.

## EMOLLIENTS AND PROTECTIVES

### EMOLLIENTS AND PROTECTIVES

#### Silicone products

**DIMETHICONE-350 + GLYCEROL**

**Restricted benefit**
For colostomy and ileostomy use

**Restricted benefit**
For use by paraplegic and quadriplegic patients

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4551M</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g/g) cream, 500 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>26.75</td>
<td>6.10</td>
<td>Silic 15</td>
</tr>
<tr>
<td>4556T</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g/g) cream, 75 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.87</td>
<td>6.10</td>
<td>Silic 15</td>
</tr>
</tbody>
</table>

#### Soft paraffin and fat products

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4041Q</td>
<td>wool alcohols 6% (60 mg/g) ointment, 100 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.52</td>
<td>6.10</td>
<td>Eucerin</td>
</tr>
</tbody>
</table>

#### Carbamide products

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4042R</td>
<td>urea 10% (100 mg/g) cream, 100 g</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>12.53</td>
<td>6.10</td>
<td>Aquacare H.P.</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Urederm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Calmurd</td>
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</table>

#### Other emollients and protectives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $ for Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4518T</td>
<td>carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.19</td>
<td>6.10</td>
<td>Orabase</td>
</tr>
</tbody>
</table>

## PROTECTIVES AGAINST UV-RADIATION

### Protectives against UV-radiation for topical use

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4307Q</td>
<td>SUNSCREENS Cream 75 g, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.39</td>
<td>6.10</td>
<td>Sunsense Sensitive SPF 50+</td>
</tr>
<tr>
<td>4546G</td>
<td>SUNSCREENS Lotion (non-alcoholic) 125 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>16.32</td>
<td>6.10</td>
<td>Aquasun Lotion SPF 18</td>
</tr>
</tbody>
</table>

### Other Protectives against UV-radiation

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4122Y</td>
<td>SKIN EMOULLIENT Bath oil 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.10</td>
<td>Alpha Keri Bath Oil</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
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<td>..</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QV Bath Oil</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hamilton Skin Therapy Oil</td>
</tr>
<tr>
<td>4107E</td>
<td>SKIN EMOULLIENT Lotion 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.10</td>
<td>Alpha Keri Lotion</td>
</tr>
</tbody>
</table>

### Other Protectives against UV-radiation

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4551M</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g/g) cream, 500 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>26.75</td>
<td>6.10</td>
<td>Silic 15</td>
</tr>
<tr>
<td>4556T</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g/g) cream, 75 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.87</td>
<td>6.10</td>
<td>Silic 15</td>
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</tbody>
</table>

### Soft paraffin and fat products

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4041Q</td>
<td>wool alcohols 6% (60 mg/g) ointment, 100 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.52</td>
<td>6.10</td>
<td>Eucerin</td>
</tr>
</tbody>
</table>

### Carbamide products

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4042R</td>
<td>urea 10% (100 mg/g) cream, 100 g</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>12.53</td>
<td>6.10</td>
<td>Aquacare H.P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>..</td>
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<td></td>
<td></td>
<td></td>
<td>Urederm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Calmurd</td>
</tr>
</tbody>
</table>

### Other emollients and protectives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4518T</td>
<td>carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.19</td>
<td>6.10</td>
<td>Orabase</td>
</tr>
</tbody>
</table>

### Other Protectives against UV-radiation

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4122Y</td>
<td>SKIN EMOULLIENT Bath oil 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.10</td>
<td>Alpha Keri Bath Oil</td>
</tr>
<tr>
<td>4107E</td>
<td>SKIN EMOULLIENT Lotion 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.10</td>
<td>Alpha Keri Lotion</td>
</tr>
</tbody>
</table>

### Protectives against UV-radiation for topical use

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4307Q</td>
<td>SUNSCREENS Cream 75 g, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.39</td>
<td>6.10</td>
<td>Sunsense Sensitive SPF 50+</td>
</tr>
<tr>
<td>4546G</td>
<td>SUNSCREENS Lotion (non-alcoholic) 125 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>16.32</td>
<td>6.10</td>
<td>Aquasun Lotion SPF 18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sunsense Ultra SPF 50+</td>
</tr>
</tbody>
</table>
## ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

#### Anesthetics for topical use

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4308R</td>
<td>lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL</td>
<td>‡1 .. ..</td>
<td>95.37</td>
<td>6.10</td>
<td>Xylocaine Viscous</td>
<td>AP</td>
<td></td>
</tr>
</tbody>
</table>

### Other antipruritics

#### PineTar with Triethanolamine Lauryl Sulfate

Note

For patients who have failed to respond to simple moisturising agents.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4408B</td>
<td>PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL</td>
<td>‡1 2 ..</td>
<td>23.26</td>
<td>6.10</td>
<td>Pinetarsol</td>
<td>EO</td>
<td></td>
</tr>
</tbody>
</table>

## ANTIPSORIATICS

## ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

### ANTIBIOTICS FOR TOPICAL USE

#### Other antibiotics for topical use

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4348W</td>
<td>mupirocin 2% (20 mg/g) cream, 15 g</td>
<td>‡1 .. ..</td>
<td>17.59</td>
<td>6.10</td>
<td>Bactroban</td>
<td>GK</td>
<td></td>
</tr>
<tr>
<td>4350Y</td>
<td>mupirocin 2% (20 mg/g) ointment, 15 g</td>
<td>‡1 .. ..</td>
<td>17.59</td>
<td>6.10</td>
<td>Bactroban</td>
<td>GK</td>
<td></td>
</tr>
</tbody>
</table>

### CHEMOTHERAPEUTICS FOR TOPICAL USE

#### Antivirals

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4390C</td>
<td>podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g</td>
<td>‡1 .. ..</td>
<td>53.00</td>
<td>6.10</td>
<td>Wartec Cream</td>
<td>GK</td>
<td></td>
</tr>
<tr>
<td>4566H</td>
<td>podophyllotoxin 0.5% solution, 3.5 mL</td>
<td>‡1 .. ..</td>
<td>40.09</td>
<td>6.10</td>
<td>Condyline Paint</td>
<td>NQ</td>
<td></td>
</tr>
</tbody>
</table>

### Other chemotherapeutics

#### INGEnol Mebutate

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2464Q</td>
<td>ingenol mebutate 0.015% gel, 3 x 470 mg tubes</td>
<td>1 .. ..</td>
<td>139.60</td>
<td>6.10</td>
<td>Picato</td>
<td>LO</td>
<td></td>
</tr>
</tbody>
</table>

#### INGEnol Mebutate

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1247</td>
<td>.. .. ..</td>
<td>.. ..</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
</tbody>
</table>

#### Note

For patients who have failed to respond to simple moisturising agents.
**DERMATOLOGICALS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Clinical criteria:**
Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

2468X ingleng mebutate 0.05% gel, 2 x 470 mg tubes 1 .. .. 139.60 6.10 Picato LO

### CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

#### CORTICOSTEROIDS, PLAIN

**Corticosteroids, potent (group III)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**BETAMETHASONE VALERATE**

Betamethasone (as valerate) 0.1% (1 mg/g) cream, 30 g ‡1 2 .. .. 22.77 6.10 Betnovate QA

Betamethasone (as valerate) 0.1% (1 mg/g) ointment, 30 g ‡1 2 .. .. 22.77 6.10 Betnovate QA

**MOMETASONE**

Note
Application to large areas of skin for longer than four weeks is not recommended.

4342M mometasone furoate 0.1% (1 mg/g) cream, 50 g ‡1 .. .. .. 33.82 6.10 Elocon MK

4343N mometasone furoate 0.1% (1 mg/g) ointment, 50 g ‡1 .. .. .. 33.82 6.10 Elocon MK

### ANTISEPTICS AND DISINFECTANTS

#### Iodine products

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

POVIDONE-IODINE

povidone-iodine 10% solution, 100 mL ‡1 .. .. .. 22.45 6.10 Betadine Antiseptic Liquid SW

### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**COAL TAR SOLUTION + TAR + SALICYLIC ACID**

coc tar solution 1% (10 mg/g) + tar 1% (10 mg/g) + salicylic acid 2% (20 mg/g) solution, 250 mL ‡1 2 .. .. 19.18 6.10 Sebitar EO

**SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS**

SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1 ‡1 2 .. .. 20.72 6.10 Ionil-T GA

**SELENIUM SULFIDE**

Selenium sulfide 2.5% (25 mg/mL) shampoo, 125 mL ‡1 .. .. .. 14.48 6.10 Selsun DQ

**TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR**

tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL ‡1 2 .. .. 24.48 6.10 Polytar GK

### Wart and anti-corn preparations

#### LACTIC ACID + SALICYLIC ACID

lactic acid 16.7% (167 mg/mL) + salicylic acid 16.7% (167 mg/mL) application, 15 mL ‡1 .. .. .. 18.49 6.10 Duofilm Solution GK

### Other dermatologicales
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>DICLOFENAC</td>
<td>Authority required</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum quantity of four tubes (original + 3 repeats) in 12 months.</td>
<td></td>
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<tr>
<td>4046Y</td>
<td>diclofenac sodium 3% gel, 25 g</td>
<td>‡1</td>
<td>3</td>
<td>...</td>
<td>58.53</td>
<td>6.10</td>
</tr>
<tr>
<td>ICHTHAMMOL</td>
<td>Note</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For patients who have failed to respond to simple moisturising agents.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4281H</td>
<td>ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1</td>
<td>‡1</td>
<td>2</td>
<td>...</td>
<td>18.44</td>
<td>6.10</td>
</tr>
<tr>
<td>ICHTHAMMOL + ZINC OXIDE</td>
<td>Note</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>For patients who have failed to respond to simple moisturising agents.</td>
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<td></td>
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</tr>
<tr>
<td>4280G</td>
<td>ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g</td>
<td>‡1</td>
<td>2</td>
<td>...</td>
<td>18.44</td>
<td>6.10</td>
</tr>
<tr>
<td>IMIQUIMOD</td>
<td>Authority required</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solar keratosis</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Clinical criteria: Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note</td>
<td>Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4134N</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
<td>1</td>
<td>1</td>
<td>...</td>
<td>135.72</td>
<td>6.10</td>
</tr>
<tr>
<td>4134N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10106X</td>
<td>imiquimod 5% cream, 2 x 2 g pump packs</td>
<td>1</td>
<td>1</td>
<td>...</td>
<td>135.72</td>
<td>6.10</td>
</tr>
<tr>
<td>IMIQUIMOD</td>
<td>Authority required</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4559Y</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
<td>1</td>
<td>1</td>
<td>...</td>
<td>135.72</td>
<td>6.10</td>
</tr>
<tr>
<td>PANTHENOL</td>
<td>Note</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4510J</td>
<td>panthenol conditioner, 200 g</td>
<td>‡1</td>
<td>2</td>
<td>...</td>
<td>14.59</td>
<td>6.10</td>
</tr>
<tr>
<td>PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE DISODIUM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4549K</td>
<td>paraffin light liquid 3.5% (35 mg/mL) + cocoamphodiacetate disodium 3% (30 mg/mL) lotion, 500 mL</td>
<td>‡1</td>
<td>2</td>
<td>...</td>
<td>21.08</td>
<td>6.10</td>
</tr>
<tr>
<td>ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4497Q</td>
<td>zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-purified 18.07% (180.7 mg/g) powder: dusting, 100 g</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>12.59</td>
<td>6.10</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
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<tr>
<td>GENITO URINARY SYSTEM AND SEX HORMONES</td>
<td></td>
<td></td>
<td></td>
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</table>

### GENETO URINARY SYSTEM AND SEX HORMONES

#### GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

#### ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

**Antibiotics**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4013F</td>
<td>NYSTATIN nystatin 20 000 international units/g vaginal cream, 75 g</td>
<td>‡1 1 ..</td>
<td>14.13 6.10</td>
<td>Nilstat QA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4016J</td>
<td>CLOTRIMAZOLE clotrimazole 1% (10 mg/g) cream, 35 g</td>
<td>‡1 .. ..</td>
<td>14.03 6.10</td>
<td>a Pharmacy Action FemCream GQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4017K</td>
<td>clotrimazole 2% (20 mg/g) cream, 20 g</td>
<td>‡1 .. ..</td>
<td>15.42 6.10</td>
<td>a APO-Clotrimazole 6 Day TX Cream</td>
<td></td>
<td></td>
<td></td>
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</tbody>
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#### OTHER GYNECOLOGICALS

### OTHER GYNECOLOGICALS

#### ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4434J</td>
<td>acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g</td>
<td>‡1 .. ..</td>
<td>33.24 6.10</td>
<td>Aci-Jel CU</td>
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### UROLOGICALS

#### Drugs used in erectile dysfunction

**ALPROSTADIL**

*Authority required*

Males with vasculogenic, psychogenic or neurogenic erectile dysfunction

**Clinical criteria:**

Patient must have a specific accepted war-caused or service-related disability.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10031Y</td>
<td>alprostadil 10 microgram injection [1 x 10 microgram vial] &amp; (6) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3 ..</td>
<td>*105.82 6.10</td>
<td>Caverject PF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10030X</td>
<td>alprostadil 20 microgram injection [1 x 20 microgram vial] &amp; (6) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3 ..</td>
<td>*133.18 6.10</td>
<td>Caverject PF</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SILDENAFIL**

*Authority required*

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4586J</td>
<td>sildenafil 100 mg tablet, 4</td>
<td>1 5 ..</td>
<td>73.33 6.10</td>
<td>a APO-Sildenafil TX</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4584G</td>
<td>sildenafil 25 mg tablet, 4</td>
<td>1 5 ..</td>
<td>55.21 6.10</td>
<td>a APO-Sildenafil TX</td>
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<td></td>
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</table>

### 1251
<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4585H</td>
<td>sildenafil 50 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>64.32 a</td>
<td>6.10 a Viagra</td>
<td>PF</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4596X</td>
<td>tadalafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>98.96 a</td>
<td>6.10 Cialis</td>
<td>LY</td>
</tr>
<tr>
<td>4597Y</td>
<td>tadalafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>98.96 a</td>
<td>6.10 Cialis</td>
<td>LY</td>
</tr>
<tr>
<td>4290T</td>
<td>vardenafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>73.13 a</td>
<td>6.10 Levitra</td>
<td>BN</td>
</tr>
<tr>
<td>4302K</td>
<td>vardenafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>83.86 a</td>
<td>6.10 Levitra</td>
<td>BN</td>
</tr>
</tbody>
</table>

**TADALAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4596X</td>
<td>tadalafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>98.96 a</td>
<td>6.10 Cialis</td>
<td>LY</td>
</tr>
<tr>
<td>4597Y</td>
<td>tadalafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>98.96 a</td>
<td>6.10 Cialis</td>
<td>LY</td>
</tr>
</tbody>
</table>

**VARDENAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4290T</td>
<td>vardenafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>73.13 a</td>
<td>6.10 Levitra</td>
<td>BN</td>
</tr>
<tr>
<td>4302K</td>
<td>vardenafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>83.86 a</td>
<td>6.10 Levitra</td>
<td>BN</td>
</tr>
</tbody>
</table>

**Other urologicals**

**BICARBONATE + CITRATE + TARTARIC ACID**

**Restricted benefit**

For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4049D</td>
<td>sodium bicarbonate 1.76 g + citrate</td>
<td>§1</td>
<td>4</td>
<td>...</td>
<td>13.89 a</td>
<td>6.10 Uracol</td>
<td>GN</td>
</tr>
<tr>
<td></td>
<td>sodium 630 mg + citrate 720 mg + tartaric acid 890 mg oral liquid: powder for, 28 x 4 g sachets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY**

**Alpha-adrenoreceptor antagonists**

**ALFUZOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4277D</td>
<td>alfuzosin hydrochloride 10 mg tablet: modified release, 30 tablets</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>63.70 a</td>
<td>6.10 Xatral SR</td>
<td>SW</td>
</tr>
</tbody>
</table>

**DUTASTERIDE + TAMSULOSIN**

**Authority required**

Benign prostatic hyperplasia.

**Clinical criteria:**

Patient must be one in whom surgery is inappropriate: OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10102Q</td>
<td>dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>35.63 a</td>
<td>6.10 Duodart 500ug/400ug</td>
<td>GK</td>
</tr>
</tbody>
</table>

**TAMSULOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4070F</td>
<td>tamsulosin hydrochloride 400 microgram tablet: modified release, 30</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>63.70 a</td>
<td>6.10 Flomaxtra</td>
<td>LS</td>
</tr>
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</table>

**TERAZOSIN**
## GENITO URINARY SYSTEM AND SEX HORMONES

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tbody>
<tr>
<td><strong>Authority required</strong></td>
<td>Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated</td>
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<tr>
<td>4396J</td>
<td>terazosin 1 mg tablet [7 tablets] (&amp;) terazosin 2 mg tablet [7 tablets], 14</td>
<td>1</td>
<td>..</td>
<td>20.39</td>
<td>6.10</td>
<td>Hytrin</td>
<td>GO</td>
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<tr>
<td>4399M</td>
<td>terazosin 10 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>86.40</td>
<td>6.10</td>
<td>Hytrin</td>
</tr>
<tr>
<td>4397K</td>
<td>terazosin 2 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>42.03</td>
<td>6.10</td>
<td>Hytrin</td>
</tr>
<tr>
<td>4398L</td>
<td>terazosin 5 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>58.53</td>
<td>6.10</td>
<td>Hytrin</td>
</tr>
</tbody>
</table>

**Testosterone-5-alpha reductase inhibitors**

**DUTASTERIDE**

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

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<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10095H</td>
<td>dutasteride 500 microgram capsule, 30</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>30.77</td>
<td>6.10</td>
<td>Avodart</td>
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</table>

**FINASTERIDE**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

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<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4303L</td>
<td>finasteride 5 mg tablet, 28</td>
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<td>5</td>
<td>..</td>
<td>91.60</td>
<td>6.10</td>
<td>a</td>
</tr>
<tr>
<td></td>
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<td>Pharmacy Choice Finasteride</td>
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<td>4233T</td>
<td>finasteride 5 mg tablet, 30</td>
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<td>5</td>
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<td>78.03</td>
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<td>Finasteride Alphapharm</td>
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a

1253
### ANTIBACTERIALS FOR SYSTEMIC USE

#### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>4115N</td>
<td>azithromycin 500 mg tablet, 3</td>
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<td>..</td>
<td>..</td>
<td>31.85</td>
<td>6.10</td>
<td>APO-Azithromycin TX</td>
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<td>Azithromycin Sandoz SZ</td>
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<td>Zedd 500 QA</td>
</tr>
</tbody>
</table>

*Upper and lower respiratory tract infections*
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

*Pyrimidine analogues*

**FLUOROURACIL**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4222F</td>
<td>fluorouracil 5% (50 mg/g) cream, 20 g</td>
<td>‡1</td>
<td>..</td>
<td>60.96</td>
<td>6.10</td>
<td>6.10</td>
<td>Efudix IA</td>
</tr>
</tbody>
</table>

IMMUNOSUPPRESSANTS

*Tumor necrosis factor alpha (TNF-) inhibitors*

**INFliximab**

*Authority required*

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

1. (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
2. (b) Proven erosive rheumatoid arthritis without end-stage disease;
3. Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
4. No history of active tuberculosis requiring treatment in the last 3 years;
5. No history of opportunistic infection in the last 2 months;
6. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

*Authority required*

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

1. There is improvement in ESR and/or CRP; and
2. An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

*Note*

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998
Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans’ Affairs
GPO Box 9998
BRISBANE QLD 4001

<table>
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<th>No. of Rpts</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>infliximab 100 mg injection, 1 x 100 mg vial</td>
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<td>6.10</td>
<td>6.10</td>
<td>Remicade JC</td>
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# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-Steroids

**Acetic acid derivatives and related substances**

**DICLOFENAC + MISOPROSTOL**

*Authority required*

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease

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<tr>
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## TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

**Preparations with salicylic acid derivatives**

**METHYL SALICYLATE**

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<thead>
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<th>No. of Rpts</th>
<th>Premium Price for Max. Qty $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>4026X</td>
<td>methyl salicylate 25% (0.25 mL/mL) liniment, 100 mL</td>
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<td></td>
<td>10.28</td>
<td>6.10</td>
<td>Gold Cross BI</td>
<td></td>
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<tr>
<td>4023R</td>
<td>methyl salicylate 50% (500 mg/g) ointment, 100 g</td>
<td>‡1 1 ..</td>
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<td>12.51</td>
<td>6.10</td>
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<td></td>
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<tr>
<td>4022Q</td>
<td>methyl salicylate 25% (250 mg/g) + menthol 4% (40 mg/g) + eucalyptus oil 10% (100 mg/g) cream, 100 g</td>
<td>‡1 1 ..</td>
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<td>14.36</td>
<td>6.10</td>
<td>Gold Cross BI</td>
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## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

**RISEDRONATE**

*Authority required*

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

<table>
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<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2191H</td>
<td>RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4</td>
<td>1 5 ..</td>
<td></td>
<td>42.11</td>
<td>6.10</td>
<td>Actonel EC UA</td>
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<tr>
<td>4444X</td>
<td>risedronate sodium 35 mg tablet, 4</td>
<td>1 5 ..</td>
<td></td>
<td>42.11</td>
<td>6.10</td>
<td>Cris Once-a-Week AF</td>
<td></td>
</tr>
<tr>
<td>4443W</td>
<td>risedronate sodium 5 mg tablet, 28</td>
<td>1 5 ..</td>
<td></td>
<td>42.11</td>
<td>6.10</td>
<td>Actonel UA</td>
<td></td>
</tr>
</tbody>
</table>

**Bisphosphonates, combinations**

**ALENDRONATE + COLECALCIFEROL**

*Authority required*

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

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<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2224C</td>
<td>alendronate 70 mg + colecaciferol 140 microgram tablet, 4</td>
<td>1 5 ..</td>
<td></td>
<td>45.51</td>
<td>6.10</td>
<td>Alerondronate plus D3- DRLA RZ</td>
<td></td>
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<tr>
<td>2194L</td>
<td>alendronate 70 mg + colecaciferol 70 microgram tablet, 4</td>
<td>1 5 ..</td>
<td></td>
<td>45.51</td>
<td>6.10</td>
<td>Fosamax Plus 70 mg/140 mcg MK</td>
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**ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**
<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
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</thead>
<tbody>
<tr>
<td>Authority required For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)</td>
<td>2273P alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&amp;) calcium (as carbonate) 500 mg tablet [48], 1 pack</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.51</td>
<td>6.10</td>
</tr>
<tr>
<td>Authority required For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)</td>
<td>2220W RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.73</td>
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<tr>
<td>Authority required For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)</td>
<td>4059P risedronate sodium 35 mg tablet [4] (&amp;) calcium (as carbonate) 500 mg tablet [24], 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.73</td>
<td>6.10</td>
</tr>
<tr>
<td>Authority required For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)</td>
<td>2254P RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.73</td>
<td>6.10</td>
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## NERVOUS SYSTEM

### ANALGESICS

#### OPIOIDS

**Natural opium alkaloids**

**MORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for

(i) chronic severe disabling pain associated with proven malignant neoplasm; or

(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

<table>
<thead>
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<td>morphine sulfate 200 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>122.20</td>
<td>6.10</td>
<td>MS Contin MF</td>
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#### OTHER ANALGESICS AND ANTIPYRETICS

**Salicylic acid and derivatives**

#### Anilides

**PARACETAMOL + CODEINE**

<table>
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<th>Code</th>
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<tr>
<td>4286N</td>
<td>aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40</td>
<td>1</td>
<td>2</td>
<td>14.52</td>
<td>6.10</td>
<td>Aspalgin 40 QA</td>
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</table>

**Other analgesics and antipyretics**

#### GABAPENTIN

**Authority required**

To be approved for the treatment of refractory neuropathic pain not controlled by other drugs

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<td>gabapentin 100 mg capsule, 100</td>
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<td>5</td>
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<td>6.10</td>
<td>a APO-Gabapentin TX</td>
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<td>a Gabapentin Aspen 100 FM</td>
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<td>a Gabatine 100 QA</td>
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<td>a Neurontin PF</td>
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<td>a Nupentin 100 AF</td>
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<td>4592Q</td>
<td>gabapentin 300 mg capsule, 100</td>
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<td>27.43</td>
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<td>a DBL Gabapentin HH</td>
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<td>a Gabapentin Aspen 300 FM</td>
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<td>a Gabatine 300 QA</td>
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<td>a Gantin GN</td>
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<td>5</td>
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<td>5</td>
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<td>63.81</td>
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**PSYCHOLEPTICS**

**ANXIOLYTICS**

* Benzodiazepine derivatives

**BROMAZEPAM**

* **Authority required**
  Patients with terminal disease

* **Authority required**
  Patients with refractory phobic or anxiety states

* **Note**
  For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4150K  bromazepam 3 mg tablet, 30   2   ..   ..   *29.82  6.10  Lexotan RO

4151L  bromazepam 6 mg tablet, 30   2   ..   ..   *36.44  6.10  Lexotan RO

* **Azaspirodecane derivatives**

**BUSPIRONE**

* **Authority required**
  For the short-term treatment of anxiety

4145E  buspirone hydrochloride 10 mg tablet, 50   1   ..   ..   55.18  6.10  Buspar QA

4144D  buspirone hydrochloride 5 mg tablet, 50   1   ..   ..   38.33  6.10  Buspar QA

**HYPNOTICS AND SEDATIVES**

* Benzodiazepine derivatives

**FLUNITRAZEPAM**

* **Authority required**
  Patients with terminal disease

* **Authority required**
  Patients with refractory phobic or anxiety states

* **Note**
  For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4216X  flunitrazepam 1 mg tablet, 30   1   ..   ..   15.22  6.10  Hypnodorm AF

* **Benzodiazepine related drugs**

**ZOPICLONE**
NERVOUS SYSTEM

**Restricted benefit**
For the short-term treatment of insomnia

<table>
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<tr>
<th>Code</th>
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<td>4522B</td>
<td>zopiclone 7.5 mg tablet, 30</td>
<td>1</td>
<td>..</td>
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<td>22.10</td>
<td>6.10</td>
<td>Imrest AF</td>
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<td>25.25</td>
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<td>Imovane SW</td>
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OTHER NERVOUS SYSTEM DRUGS

**DRUGS USED IN ADDICTIVE DISORDERS**

*Drugs used in nicotine dependence*

**NICOTINE**

**Authority required**
Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program

**Note**
Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>4577X</td>
<td>nicotine 10 mg/16 hours patch, 7</td>
<td>2</td>
<td>..</td>
<td></td>
<td>*55.12</td>
<td>6.10</td>
<td>Nicorette Patch JT</td>
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<tr>
<td>4572P</td>
<td>nicotine 14 mg/24 hours patch, 7</td>
<td>2</td>
<td>..</td>
<td></td>
<td>*54.90</td>
<td>6.10</td>
<td>QuitX AF</td>
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<td>4578Y</td>
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<td>2</td>
<td></td>
<td>*69.08</td>
<td>6.10</td>
<td>Nicabate CQ 14 GC</td>
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<tr>
<td>4573Q</td>
<td>nicotine 21 mg/24 hours patch, 7</td>
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<td>2</td>
<td></td>
<td>*58.02</td>
<td>6.10</td>
<td>QuitX AF</td>
</tr>
<tr>
<td>4576W</td>
<td>nicotine 5 mg/16 hours patch, 7</td>
<td>2</td>
<td>..</td>
<td></td>
<td>*69.08</td>
<td>6.10</td>
<td>Nicabate CQ 21 GC</td>
</tr>
<tr>
<td>4571N</td>
<td>nicotine 7 mg/24 hours patch, 7</td>
<td>2</td>
<td>..</td>
<td></td>
<td>*51.74</td>
<td>6.10</td>
<td>QuitX AF</td>
</tr>
<tr>
<td>Code</td>
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<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------</td>
<td>------------------</td>
<td>-------------</td>
<td>-----------</td>
<td>-------------------------------</td>
<td>------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>4325P</td>
<td>MEBENDAZOLE mebendazole 100 mg tablet, 6</td>
<td>1</td>
<td>..</td>
<td>15.26</td>
<td>6.10</td>
<td></td>
<td>Vermox IA</td>
</tr>
</tbody>
</table>
## RESPIRATORY SYSTEM

### NASAL PREPARATIONS

#### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

**Sympathomimetics, plain**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4378K</td>
<td>oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.49</td>
<td>6.10</td>
<td></td>
<td>Drixine BN</td>
</tr>
<tr>
<td>4379L</td>
<td>oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 18 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.10</td>
<td>6.10</td>
<td></td>
<td>Logicin Rapid Relief QA</td>
</tr>
</tbody>
</table>

**Antiallergic agents, excl. corticosteroids**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4468E</td>
<td>cromoglycate sodium 2% (20 mg/mL) nasal spray, 26 mL</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>23.25</td>
<td>6.10</td>
<td></td>
<td>Rynacrom SW</td>
</tr>
<tr>
<td>4311X</td>
<td>levocabastine 0.05% (500 microgram/mL) nasal spray, 100 actuations</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.58</td>
<td>6.10</td>
<td></td>
<td>Livostin JT</td>
</tr>
</tbody>
</table>

**Corticosteroids**

**Budesonide**

**Restricted benefit**

Severe intractable rhinitis

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4092J</td>
<td>budesonide 64 microgram/actuation nasal spray, 120 actuations</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>37.51</td>
<td>6.10</td>
<td></td>
<td>Budamox Aqueous PM</td>
</tr>
</tbody>
</table>

**Other nasal preparations**

**Ipratropium**

**Restricted benefit**

Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4089F</td>
<td>ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>23.93</td>
<td>6.10</td>
<td></td>
<td>Atrovent Nasal Aqueous BY</td>
</tr>
<tr>
<td>4090G</td>
<td>ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>30.81</td>
<td>6.10</td>
<td></td>
<td>Atrovent Nasal Forte BY</td>
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**NASAL DECONGESTANTS FOR SYSTEMIC USE**

**Sympathomimetics**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4029C</td>
<td>pseudoephedrine hydrochloride 60 mg tablet, 12</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>10.61</td>
<td>6.10</td>
<td></td>
<td>Pharmacy Action Sinus &amp; Nasal Decongestant Relief GQ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>..</td>
<td>11.36</td>
<td>6.10</td>
<td></td>
<td>Logicin Sinus QA</td>
</tr>
</tbody>
</table>

### COUGH AND COLD PREPARATIONS

#### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

**Expectorants**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4074K</td>
<td>ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL</td>
<td>‡1</td>
<td>4</td>
<td>..</td>
<td>9.52</td>
<td>6.10</td>
<td></td>
<td>Gold Cross BI</td>
</tr>
</tbody>
</table>

#### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

**Opium alkaloids and derivatives**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
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<th>Max. Qty (Packs)</th>
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</table>
### RESPIRATORY SYSTEM

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4071G</td>
<td>pholcodine 1 mg/mL oral liquid, 100 mL ‡</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>9.36</td>
<td>6.10</td>
<td>Gold Cross BI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>14.95</td>
<td>6.10</td>
<td>Duro-Tuss IA</td>
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</tbody>
</table>

## ANTIHISTAMINES FOR SYSTEMIC USE

### Piperazine derivatives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4175R</td>
<td>cetirizine hydrochloride 10 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>26.28</td>
<td>6.10</td>
<td>a Pharmacy Action Cetrelief</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>29.99</td>
<td>6.10</td>
<td>a Alzene AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>33.21</td>
<td>6.10</td>
<td>a Zilarex SZ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>39.79</td>
<td>6.10</td>
<td>a Zyrtec JT</td>
</tr>
</tbody>
</table>

### Other antihistamines for systemic use

<table>
<thead>
<tr>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>4238C</td>
<td>fexofenadine hydrochloride 120 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.76</td>
<td>6.10</td>
<td>a Xergic AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>35.05</td>
<td>6.10</td>
<td>a Fexal SZ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>47.47</td>
<td>6.10</td>
<td>a Telfast 120 SW</td>
</tr>
<tr>
<td>4237B</td>
<td>fexofenadine hydrochloride 60 mg tablet, 20</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*55.33</td>
<td>6.10</td>
<td>a Telfast SW</td>
</tr>
<tr>
<td>4313B</td>
<td>loratadine 10 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.07</td>
<td>6.10</td>
<td>a Pharmacy Action Loratyne</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>33.33</td>
<td>6.10</td>
<td>a Allereze AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>43.99</td>
<td>6.10</td>
<td>a Lorano SZ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>..</td>
<td>46.26</td>
<td>6.10</td>
<td>a Claratyn BN</td>
</tr>
</tbody>
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## SENSORY ORGANS

### OPHTHALMOLOGICALS

#### DECONGESTANTS AND ANTIALLERGICS

**Sympathomimetics used as decongestants**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tbody>
<tr>
<td>4035J</td>
<td>NAPHAZOLINE</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.43</td>
<td>6.10 AG</td>
</tr>
<tr>
<td></td>
<td>naphazoline hydrochloride 0.1% eye drops, 15 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4032F</td>
<td>NAPHAZOLINE + ANTAZOLINE</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.14</td>
<td>6.10 AG</td>
</tr>
<tr>
<td></td>
<td>naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Other antiallergics

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>4310W</td>
<td>LEVOCABASTINE</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>18.58</td>
<td>6.10 JT</td>
</tr>
<tr>
<td></td>
<td>levocabastine 0.05% eye drops, 4 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### OTOLOGICALS

#### OTHER OTOLOGICALS

**Indifferent preparations**

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>4176T</td>
<td>CARBAMIDE PEROXIDE</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.66</td>
<td>6.10 KY</td>
</tr>
<tr>
<td></td>
<td>carbamide peroxide 6.5% ear drops, 12 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4180B</td>
<td>DICHLOROBENZENE WITH CHLOR BUTOL AND ARACHIS OIL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>14.42</td>
<td>6.10 UN</td>
</tr>
<tr>
<td></td>
<td>DICHLOROBENZENE with CHLOR BUTOL and ARACHIS OIL Ear drops, ortho- dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4199B</td>
<td>DOCUSATE</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>14.81</td>
<td>6.10 HM</td>
</tr>
<tr>
<td></td>
<td>docusate sodium 0.5% (5 mg/mL) ear drops, 10 mL</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
### VARIOUS

#### ALL OTHER THERAPEUTIC PRODUCTS

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4470G</td>
<td>Resonium-A SW</td>
</tr>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</tr>
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<tbody>
<tr>
<td>4470G</td>
<td>POLYSTYRENE SULFONATE SODIUM</td>
<td>¥1</td>
<td>2</td>
<td>..</td>
<td>71.46</td>
<td>6.10</td>
<td>Resonium-A SW</td>
</tr>
</tbody>
</table>

*Note: ¥1 indicates a specific condition or restriction.*
### WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound’s healing process should be undertaken.

### DRESSINGS

#### PINK EPITHELIALISING WOUND

**Aim:** To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

- **(A) Covering**
  - Film;
  - Film Island

- **(B) Absorbing**
  - Foam (Light Exudate);
  - Hydroactive (Superficial Wound—Light Exudate)

#### RED GRANULATING WOUND

**Aims:** (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

- **(A) Absorbing**
  - Foam (Light Exudate);
  - Hydroactive (Superficial Wound—Light Exudate);
  - Hydrocolloid (Superficial Wound—Light Exudate)

- **(B) Moisture donating**
  - Hydrogel—Amorphous;
  - Hydrogel—Sheet

### LIGHT EXUDATE:

**Superficial**

- **(A) Absorbing**
  - Foam (Light Exudate);
  - Hydroactive (Superficial Wound—Light Exudate);
  - Hydrocolloid (Superficial Wound—Light Exudate)

- **(B) Moisture donating**
  - Hydrogel—Amorphous

**Cavity**

- Hydrocolloid (Cavity Wound)

### HIGH EXUDATE:

**Superficial**

- **(A) Absorbing**
  - Alginate (Superficial Wound);
  - Foam—Heavy Exudate;
  - Hydroactive (Superficial Wound—Moderate Exudate);
  - Hydrocolloid (Superficial Wound—Moderate/High Exudate)

- **(B) Moisture donating**
  - Alginate (Cavity Wound);
  - Foam—Moderate Exudate (see “cavity conforming” product);
  - Hydroactive (Cavity Wound);
  - Hydrocolloid (Cavity Wound)

**Cavity**

- Hydroactive (Cavity Wound);

- Hydrocolloid (Cavity Wound)

- NOT APPROPRIATE
### Various

<table>
<thead>
<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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</tr>
</thead>
</table>

#### Yellow Sloppy Wound

**Aims:** (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

**Light Exudate:**

- **(A) Absorbing**
  - Cadexomer Iodine;
  - Foam—Light Exudate;
  - Foam with Charcoal;
  - Hydroactive (Superficial Wound—Moderate Exudate);
  - Hydrocolloid (Superficial Wound—Moderate Exudate)

- **(B) Moisture Donating**
  - Hydrogel—Amorphous;
  - Hydrogel—Sheet

**High Exudate:**

- **(A) Absorbing**
  - Alginate (Superficial Wound);
  - Cadexomer Iodine;
  - Foam—Heavy Exudate;
  - Hydroactive (Superficial Wound—Moderate/High Exudate);
  - Hydrocolloid (Superficial Wound—Moderate/High Exudate)

- **(B) Moisture Donating**
  - Hydrogel—Amorphous;
  - Hydrogel—Sheet

**Black Necrotic Wound**

**Aim:** To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a Light Exudate.)

**Dry / Light Exudate:**

- **(A) Absorbing**
  - Hydroactive (Superficial Wound—Light Exudate);
  - Hydrocolloid (Superficial Wound—Light/Moderate Exudate)

- **(B) Moisture Donating**
  - Hydrogel—Amorphous;
  - Hydrogel—Sheet

#### Infected Wounds

**Aims:** (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

#### Malodorous Wounds

**Aims:** (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

**Products:** Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

#### Minor Skin Trauma

**Aims:** (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.
<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td><strong>LUBRICATING AGENT</strong></td>
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<tr>
<td>4306P</td>
<td>lubricating agent jelly, 100 g</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>10.47</td>
<td>6.10</td>
<td>Lubri-Gel PP</td>
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<tr>
<td></td>
<td><strong>BANDAGE ABSORBENT WOOL</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4653X</td>
<td>bandage absorbent wool 10 cm x 3 m bandage, 1</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.66</td>
<td>6.10</td>
<td>Surepress 650948 CC</td>
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<tr>
<td></td>
<td><strong>BANDAGE CALICO</strong></td>
<td></td>
<td></td>
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<td>Smith &amp; Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith &amp; Nephew Customer Service on 13 13 60. Smith &amp; Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.</td>
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<tr>
<td>4717G</td>
<td>bandage calico large bandage: triangular, 1 bandage</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>13.38</td>
<td>6.10</td>
<td>Handy 36361414 BV</td>
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<td></td>
<td><strong>BANDAGE COMPRESSION</strong></td>
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<td></td>
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<td></td>
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<tr>
<td></td>
<td>Treatment of varicose and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4654Y</td>
<td>BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*76.11</td>
<td>6.10</td>
<td>Comprilan 01027-00 BV</td>
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<tr>
<td>4748X</td>
<td>bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*73.26</td>
<td>6.10</td>
<td>Surepress 650947 CC</td>
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</tr>
<tr>
<td>4657D</td>
<td>bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*78.91</td>
<td>6.10</td>
<td>Setopress 3505 MH</td>
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</tbody>
</table>

**ORDERING HARTMANN PRODUCTS**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**ORDERING COLOPLAST PRODUCTS**

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**ORDERING MOLNLYCKE HEALTHCARE PRODUCTS**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**ALL OTHER NON-THERAPEUTIC PRODUCTS**

**Other non-therapeutic auxiliary products**

**BANDAGE COMPRESSION**

**Note**

Treatment of varicose and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**BANDAGE COMPRESSION**

**Note**

Treatment of varicose and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.
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<tbody>
<tr>
<td>4598B</td>
<td>bandage compression bandage: four layer, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*160.01</td>
<td>6.10</td>
<td>Profore Lite 66050415 SN</td>
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<tr>
<td>4658E</td>
<td>bandage compression bandage: four layer, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*234.36</td>
<td>6.10</td>
<td>Profore 66050016 SN</td>
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</table>

**BANDAGE COMPRESSION**

**Restricted benefit**

Initial treatment of venous ulcers

**Restricted benefit**

Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

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</thead>
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<tr>
<td>4050E</td>
<td>bandage compression bandage: two layer, 1 bandage</td>
<td>1</td>
<td>..</td>
<td>43.02</td>
<td>6.10</td>
<td>Coban 2</td>
<td>MM</td>
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</tbody>
</table>

**BANDAGE RETENTION COHESIVE HEAVY**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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</tr>
</thead>
<tbody>
<tr>
<td>4813H</td>
<td>bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*21.42</td>
<td>6.10</td>
<td>Peg 7423 MM</td>
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<tr>
<td>4660G</td>
<td>bandage retention cohesive heavy 10 cm x 2 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*19.70</td>
<td>6.10</td>
<td>Coban 1584 MM</td>
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<tr>
<td>4814J</td>
<td>bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*28.52</td>
<td>6.10</td>
<td>Peg 7425 MM</td>
</tr>
<tr>
<td>4811F</td>
<td>bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*14.36</td>
<td>6.10</td>
<td>Peg 7420 MM</td>
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<tr>
<td>4812G</td>
<td>bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*17.64</td>
<td>6.10</td>
<td>Peg 7422 MM</td>
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</tbody>
</table>

**BANDAGE RETENTION COHESIVE LIGHT**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4662J</td>
<td>bandage retention cohesive light 10 cm x 2 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*31.42</td>
<td>6.10</td>
<td>Handygauze Cohesive 8635 BV</td>
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<tr>
<td>4718H</td>
<td>bandage retention cohesive light 2.5 cm x 2 m bandage, 2</td>
<td>1</td>
<td>..</td>
<td>13.52</td>
<td>6.10</td>
<td>Handygauze Cohesive 8631 BV</td>
<td></td>
</tr>
<tr>
<td>4719J</td>
<td>bandage retention cohesive light 6 cm x 2 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>*16.14</td>
<td>6.10</td>
<td>Handygauze Cohesive 8633 BV</td>
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</tr>
</tbody>
</table>

**BANDAGE RETENTION COTTON CREPE**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4729X</td>
<td>bandage retention cotton crepe 10 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*25.72</td>
<td>6.10</td>
<td>Telfa 8254F KE</td>
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<tr>
<td>4727T</td>
<td>bandage retention cotton crepe 5 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.92</td>
<td>6.10</td>
<td>Tensocrepe 36301001 BV KE</td>
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<tr>
<td>4728W</td>
<td>bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*22.22</td>
<td>6.10</td>
<td>Tensocrepe 36300501 BV KE</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*25.22</td>
<td>6.10</td>
<td>Tensocrepe 36307501 BV KE</td>
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**BANDAGE TUBULAR**

**Note**

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<tr>
<td>4859R</td>
<td>bandage tubular 10 cm x 1 m bandage, 1</td>
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<td>..</td>
<td>15.32</td>
<td>6.10</td>
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<td>4855M</td>
<td>bandage tubular 6.25 cm x 1 m bandage, 1</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>6.10</td>
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<tr>
<td>4856N</td>
<td>bandage tubular 6.75 cm x 1 m bandage, 1</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>6.10</td>
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<tr>
<td>4857P</td>
<td>bandage tubular 7.5 cm x 1 m bandage, 1</td>
<td>¶1</td>
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<td>..</td>
<td>15.32</td>
<td>6.10</td>
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<tr>
<td>4858Q</td>
<td>bandage tubular 8.75 cm x 1 m bandage, 1</td>
<td>¶1</td>
<td>..</td>
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<td>15.32</td>
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**BANDAGE TUBULAR**

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<tbody>
<tr>
<td>4663K</td>
<td>bandage tubular size C (15 cm to 25 cm) bandage: straight, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>15.73</td>
<td>6.10</td>
</tr>
<tr>
<td>4664L</td>
<td>bandage tubular size D (25 cm to 43 cm) bandage: straight, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>15.73</td>
<td>6.10</td>
</tr>
<tr>
<td>4665M</td>
<td>bandage tubular size E (35 cm to 45 cm) bandage: straight, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>15.73</td>
<td>6.10</td>
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**BANDAGE TUBULAR FINGER**

<table>
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<th>Code</th>
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<tr>
<td>4798M</td>
<td>BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1</td>
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<td>..</td>
<td>..</td>
<td>18.11</td>
<td>6.10</td>
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**BANDAGE TUBULAR LIGHT WEIGHT**

**Note**

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<tbody>
<tr>
<td>4673Y</td>
<td>bandage tubular light weight 10 m bandage: large limb size, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>28.47</td>
<td>6.10</td>
</tr>
<tr>
<td>4672X</td>
<td>bandage tubular light weight 10 m bandage: medium limb size, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>27.06</td>
<td>6.10</td>
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<tr>
<td>4671W</td>
<td>bandage tubular light weight 10 m bandage: small limb size, 1 bandage</td>
<td>¶1</td>
<td>..</td>
<td>..</td>
<td>23.10</td>
<td>6.10</td>
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**BANDAGE TUBULAR LONG STOCKING**

**Note**

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<tbody>
<tr>
<td>4675C</td>
<td>bandage tubular long stocking bandage: XX/large size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*37.48</td>
<td>6.10</td>
<td>Tubigrip 1486 MH</td>
</tr>
<tr>
<td>4799N</td>
<td>bandage tubular long stocking bandage: large size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*37.46</td>
<td>6.10</td>
<td>Tubigrip 1484 MH</td>
</tr>
<tr>
<td>4797L</td>
<td>bandage tubular long stocking bandage: medium size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*37.46</td>
<td>6.10</td>
<td>Tubigrip 1483 MH</td>
</tr>
<tr>
<td>4674B</td>
<td>bandage tubular long stocking bandage: small size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*37.46</td>
<td>6.10</td>
<td>Tubigrip 1482 MH</td>
</tr>
</tbody>
</table>

**BANDAGE TUBULAR SHORT STOCKING**

**Note**

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4816L</td>
<td>bandage tubular short stocking bandage: large D/E size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*25.72</td>
<td>6.10</td>
<td>Tubigrip 1481 MH</td>
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<tr>
<td>4815K</td>
<td>bandage tubular short stocking bandage: medium C/D size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>*25.72</td>
<td>6.10</td>
<td>Tubigrip 1480 MH</td>
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<tr>
<td>4661H</td>
<td>bandage tubular short stocking bandage: small B/C size, 1 bandage</td>
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<tr>
<td>4670T</td>
<td>bandage zinc paste 10 cm x 9.1 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*29.12</td>
<td>6.10</td>
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<tr>
<td>4699R</td>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*30.00</td>
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<tr>
<td>4750B</td>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>2</td>
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<td>*79.12</td>
<td>6.10</td>
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<tr>
<td>4760M</td>
<td>bandage zinc paste 80 cm (stockings) bandage, 4</td>
<td>‡1</td>
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<td>..</td>
<td>91.26</td>
<td>6.10</td>
</tr>
<tr>
<td>2525X</td>
<td>betaine 0.1% (40 microgram/40 mL) + polyaminopropyl biguanide 0.1% (40 microgram/40 mL) 6 x 40 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>27.01</td>
<td>6.10</td>
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<tr>
<td>4937W</td>
<td>DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>163.92</td>
<td>6.10</td>
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<tr>
<td>4935R</td>
<td>DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>107.59</td>
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<tr>
<td>4931M</td>
<td>cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>70.65</td>
<td>6.10</td>
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<tr>
<td>4933P</td>
<td>cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>112.77</td>
<td>6.10</td>
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<tr>
<td>4932N</td>
<td>cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes</td>
<td>‡1</td>
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<td>..</td>
<td>113.83</td>
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<tr>
<td>4936T</td>
<td>cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets</td>
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<td>155.54</td>
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<tr>
<td>4742N</td>
<td>dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>79.32</td>
<td>6.10</td>
</tr>
<tr>
<td>4681J</td>
<td>dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1</td>
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<td>..</td>
<td>..</td>
<td>*101.26</td>
<td>6.10</td>
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<tr>
<td>4743P</td>
<td>dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5</td>
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<td>90.21</td>
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<tr>
<td>4832H</td>
<td>DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1</td>
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<td>..</td>
<td>..</td>
<td>*109.46</td>
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<td>1905G</td>
<td>DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5</td>
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<td>..</td>
<td>..</td>
<td>*115.60</td>
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<tr>
<td>4682K</td>
<td>dressing alginite cavity wound 2 g (40 cm) rope, 6 x 2 g</td>
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<td>..</td>
<td>*138.06</td>
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<tr>
<td>4831G</td>
<td>dressing alginite superficial wound 10 cm x 10 cm dressing, 1</td>
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<td>1</td>
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<td>*84.76</td>
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<td>4684M</td>
<td>dressing alginite superficial wound 5 cm x 5 cm dressing, 1</td>
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<td>1</td>
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<tr>
<td>4700J</td>
<td>dressing alginite superficial wound 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
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<td>6.10</td>
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<tr>
<td>4691X</td>
<td>dressing alginite superficial wound 15 cm x 20 cm dressing, 10</td>
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<td>1</td>
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<td>251.87</td>
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<tr>
<td>4699H</td>
<td>dressing alginite superficial wound 5 cm x 5 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
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<td>49.74</td>
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<td>4688L</td>
<td>dressing alginite superficial wound 7.5 cm x 12 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>54.57</td>
<td>6.10</td>
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<tr>
<td>4893M</td>
<td>dressing film 10 cm x 12 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>34.08</td>
<td>6.10</td>
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</table>

**DRESSING ALGINATE CAVITY WOUND**

*Note*
- This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note*
- This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note*
- Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**DRESSING FILM**

*Note*
- Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.
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<td>dressing film 10 cm x 12 cm dressing, 4</td>
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<td>19.99</td>
<td>6.10</td>
<td>Nexcare Tegaderm Transparent H1626 MM</td>
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<tr>
<td>4688R</td>
<td>dressing film 15 cm x 20 cm dressing, 1</td>
<td>6</td>
<td>..</td>
<td>*31.00</td>
<td>6.10</td>
<td>Tegaderm Transparent 1628 MM</td>
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<tr>
<td>4686P</td>
<td>dressing film 6 cm x 7 cm dressing, 8</td>
<td>‡1</td>
<td>..</td>
<td>15.98</td>
<td>6.10</td>
<td>Nexcare Tegaderm Transparent H1624 MM</td>
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<tr>
<td>4689T</td>
<td>dressing film island 5 cm x 7 cm dressing, 1</td>
<td>10</td>
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<td>*16.56</td>
<td>6.10</td>
<td>Tegaderm Transparent Island 3582 MM</td>
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<td>4690W</td>
<td>dressing film island 9 cm x 10 cm dressing, 1</td>
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<td>*28.06</td>
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<td>Tegaderm Transparent Island 3586 MM</td>
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**DRESSING FILM ISLAND**

*Note*

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<td>dressing film island 5 cm x 7.2 cm dressing, 5</td>
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<td>6.10</td>
<td>Cutifilm Plus 36361370 SN</td>
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<tr>
<td>4899W</td>
<td>dressing film island 8 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>45.92</td>
<td>6.10</td>
<td>Cutifilm Plus 36361371 SN</td>
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**DRESSING FOAM HEAVY EXUDATE**

*Note*

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

*Note*

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<td>4795J</td>
<td>dressing foam heavy exudate 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>132.80</td>
<td>6.10</td>
<td>Allevyn 66007637 SN</td>
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</table>

**DRESSING FOAM MODERATE EXUDATE**

*Note*

This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

*Note*

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<tr>
<td>4590N</td>
<td>dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>132.11</td>
<td>6.10</td>
<td>Allevyn Adhesive 66000044 SN</td>
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**DRESSING FOAM MODERATE EXUDATE**

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<td>4694C</td>
<td>dressing foam moderate exudate cavity conforming foam, 1 x 20 g sachet</td>
<td>1</td>
<td>1</td>
<td>95.09</td>
<td>6.10</td>
<td>Cavicare 4563 SN</td>
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**DRESSING FOAM WITH SILICONE**

*Note*

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<td>10017F</td>
<td>dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10</td>
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<td>55.40</td>
<td>6.10</td>
<td>Allevyn Life 66801067 SN</td>
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<tr>
<td>10029W</td>
<td>dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10</td>
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<td>..</td>
<td>79.61</td>
<td>6.10</td>
<td>Allevyn Life 66801068 SN</td>
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### TABLE 1: Variations of Wound Dressings

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<td>10023M</td>
<td>dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10</td>
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<td>..</td>
<td>110.59</td>
<td>6.10</td>
<td>Allevyn Life 66801069 MH</td>
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<td>10021K</td>
<td>dressing foam with silicone 21 cm x 21 cm dressing, 10</td>
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<td>..</td>
<td>..</td>
<td>220.75</td>
<td>6.10</td>
<td>Allevyn Life 66801070 SN</td>
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**DRESSING FOAM WITH SILICONE AND SILVER**

**Authority required**

Wound critical colonisation or chronic wounds that have not responded to conventional dressings

**Clinical criteria:**

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>2439J</td>
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<td>..</td>
<td>..</td>
<td>109.64</td>
<td>6.10</td>
<td>Mepilex Ag MH</td>
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<tr>
<td>2470B</td>
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<td>..</td>
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<td>117.40</td>
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<td>Mepilex Border Ag MH</td>
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**DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

**Note**

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<td>73.50</td>
<td>6.10</td>
<td>Allevyn Gentle Border 66800270 SN</td>
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<td>51.71</td>
<td>6.10</td>
<td>Allevyn Gentle Border 66800269 SN</td>
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</table>

**DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

**Note**

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<td>Mepilex Border 295300 MH</td>
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<td>4642H</td>
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<td>..</td>
<td>31.11</td>
<td>6.10</td>
<td>Mepilex Border 295200 MH</td>
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</tbody>
</table>

**DRESSING FOAM WITH SILICONE LIGHT EXUDATE**

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>4645L</td>
<td>dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5</td>
<td>¥1</td>
<td>..</td>
<td>..</td>
<td>38.55</td>
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<td>Mepilex Lite 284100 MH</td>
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<td>4644K</td>
<td>dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5</td>
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<td>..</td>
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<td>28.40</td>
<td>6.10</td>
<td>Mepilex Lite 284000 MH</td>
</tr>
</tbody>
</table>

**DRESSING FOAM WITH SILICONE MODERATE EXUDATE**

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4626L</td>
<td>dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5</td>
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<td>..</td>
<td>..</td>
<td>43.02</td>
<td>6.10</td>
<td>Mepilex 294100 MH</td>
</tr>
</tbody>
</table>
### DRESSING FOAM WITH SILVER

**Authority required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<td>4255Y</td>
<td>dressing foam with silver 10 cm x 10 cm dressing, 10</td>
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<tr>
<td>4259E</td>
<td>dressing foam with silver 10 cm x 10 cm dressing, 10</td>
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<td>200.72</td>
<td>6.10</td>
<td>Allevyn Ag Non-Adhesive 66800086 SN</td>
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<tr>
<td>4266M</td>
<td>dressing foam with silver 10 cm x 10 cm dressing, 10</td>
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<td>..</td>
<td>201.94</td>
<td>6.10</td>
<td>Allevyn Ag Gentle Border 66800461 SN</td>
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<tr>
<td>4258D</td>
<td>dressing foam with silver 12.5 cm x 12.5 cm dressing, 10</td>
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<tr>
<td>4270R</td>
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<td>6.10</td>
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<td>4252T</td>
<td>dressing foam with silver 7.5 cm x 7.5 cm dressing, 10</td>
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<td>..</td>
<td>135.91</td>
<td>6.10</td>
<td>Allevyn Ag Adhesive 66800073 SN</td>
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<tr>
<td>4266J</td>
<td>dressing foam with silver 7.5 cm x 7.5 cm dressing, 10</td>
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<td>..</td>
<td>135.91</td>
<td>6.10</td>
<td>Allevyn Ag Gentle Border 66800460 SN</td>
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</table>

### DRESSING GAUZE ABSORBENT

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tr>
<td>4708T</td>
<td>dressing gauze absorbent 10 cm x 10 cm cm pad, 100</td>
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<td>6.10</td>
<td>Handy 71117-06 BV</td>
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<tr>
<td>4707R</td>
<td>dressing gauze absorbent 5 cm x 5 cm cm pad, 100</td>
<td>‡1</td>
<td>..</td>
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<td>6.10</td>
<td>Handy 71117-05 BV</td>
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<tr>
<td>4768Y</td>
<td>dressing gauze eye pad, 12</td>
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<td>13.17</td>
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<td>Curity 4112 KE</td>
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</table>

### DRESSING GAUZE PARAFFIN

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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### DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tr>
<td>4845B</td>
<td>dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10</td>
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<td>2</td>
<td>24.65</td>
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<td>Bactigras 7457 SN</td>
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</table>

### DRESSING HYDROACTIVE CAVITY WOUND

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<td>4919K</td>
<td>dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5</td>
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<td>*200.48</td>
<td>6.10</td>
<td>Allevyn Plus Cavity 66047573 SN</td>
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<tr>
<td>4918W</td>
<td>dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>94.84</td>
<td>6.10</td>
<td>Allevyn Plus Cavity 66047571 SN</td>
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## DRESSING HYDROACTIVE DEBRIDEMENT

**Note**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
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<tr>
<td>4949L</td>
<td>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>85.22</td>
<td>6.10</td>
<td>TenderWet 24 Active 609210 HR</td>
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<tr>
<td>4948K</td>
<td>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>87.27</td>
<td>6.10</td>
<td>TenderWet Active Cavity 609272 HR</td>
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<tr>
<td>4950M</td>
<td>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>115.58</td>
<td>6.10</td>
<td>TenderWet 24 Active 609213 HR</td>
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</tbody>
</table>

## DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note**

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
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<tbody>
<tr>
<td>4692Y</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>55.24</td>
<td>6.10</td>
<td>CombiDERM 651031 CC</td>
</tr>
<tr>
<td>4695D</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing, island, 10 dressings</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>111.58</td>
<td>6.10</td>
<td>Tielle MTL101E KI</td>
</tr>
<tr>
<td>4693B</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>72.06</td>
<td>6.10</td>
<td>CombiDERM 651027 CC</td>
</tr>
<tr>
<td>4696E</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing, island, 5 dressings</td>
<td>‡1 .. ..</td>
<td>..</td>
<td>136.18</td>
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</table>

## DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tbody>
<tr>
<td>4927H</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>88.27</td>
<td>6.10</td>
<td>Biatain Non-adhesive 3410 CT</td>
</tr>
<tr>
<td>4929K</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>97.29</td>
<td>6.10</td>
<td>Biatain Adhesive 3420 CT</td>
</tr>
<tr>
<td>4928J</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads</td>
<td>‡1 2 ..</td>
<td>..</td>
<td>86.79</td>
<td>6.10</td>
<td>Biatain Non-adhesive 3413 CT</td>
</tr>
<tr>
<td>4930L</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads</td>
<td>‡1 2 ..</td>
<td>..</td>
<td>94.16</td>
<td>6.10</td>
<td>Biatain Adhesive 3423 CT</td>
</tr>
</tbody>
</table>

## DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<td>4906F</td>
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<td>2 1 ..</td>
<td>..</td>
<td>*113.60</td>
<td>6.10</td>
<td>Allevyn Thin 66047578 SN</td>
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<tr>
<td>4905E</td>
<td>dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
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</tr>
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## DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tr>
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<td>‡1 1 ..</td>
<td>..</td>
<td>88.27</td>
<td>6.10</td>
<td>Biatain Non-adhesive 3410 CT</td>
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<tr>
<td>4929K</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>97.29</td>
<td>6.10</td>
<td>Biatain Adhesive 3420 CT</td>
</tr>
<tr>
<td>4928J</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads</td>
<td>‡1 2 ..</td>
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<td>86.79</td>
<td>6.10</td>
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<td>4930L</td>
<td>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads</td>
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<td>1</td>
<td>...</td>
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<td>...</td>
<td>50.93</td>
<td>6.10</td>
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**DRESSING HYDROCOLLOID CAVITY WOUND**

**Note**
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>4896Q</td>
<td>dressing hydrocolloid cavity wound past, 30 g</td>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*145.46</td>
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<td>DuoDERM Paste H7930 CC</td>
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<tr>
<td>4895P</td>
<td>dressing hydrocolloid cavity wound past, 50 g</td>
<td>2</td>
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<td>...</td>
<td>*43.56</td>
<td>6.10</td>
<td>Comfeel Paste 4701 CT</td>
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</table>

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note**
This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

<table>
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<tr>
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<tr>
<td>4907G</td>
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<td>...</td>
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<td>6.10</td>
<td>DuoDERM Extra Thin H7955 CC</td>
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<td>4924E</td>
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<tr>
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<td>‡1</td>
<td>1</td>
<td>...</td>
<td>42.06</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3530 CT</td>
</tr>
<tr>
<td>4889H</td>
<td>dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>84.86</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3536 CT</td>
</tr>
</tbody>
</table>

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note**
This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note**
Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

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<tr>
<td>4947J</td>
<td>dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>48.49</td>
<td>6.10</td>
<td>Hydrocoll Thin 900758 HR</td>
</tr>
</tbody>
</table>

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MEDIUM EXUDATE**

**Note**
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

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<tr>
<td>4924E</td>
<td>dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10</td>
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<td>70.12</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3533 CT</td>
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<tr>
<td>4888G</td>
<td>dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10</td>
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<td>1</td>
<td>...</td>
<td>42.06</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3530 CT</td>
</tr>
<tr>
<td>4889H</td>
<td>dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>84.86</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3536 CT</td>
</tr>
</tbody>
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<tr>
<td>4923D</td>
<td>DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1 dressing hydrocolloid superficial wound moderate exudate 10 cm (round) dressing, 1</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>82.34</td>
<td>6.10</td>
<td>Comfeel Plus Ulcer Dressing 3110</td>
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<tr>
<td>4679G</td>
<td>dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1</td>
<td>5 .. ..</td>
<td>..</td>
<td>*59.96</td>
<td>6.10</td>
<td>Comfeel Plus Pressure Relieving 3353</td>
</tr>
<tr>
<td>4678F</td>
<td>dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1</td>
<td>5 .. ..</td>
<td>..</td>
<td>*55.51</td>
<td>6.10</td>
<td>Comfeel Plus Pressure Relieving 3350</td>
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DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tr>
<td>4921B</td>
<td>dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>86.04</td>
<td>6.10</td>
<td>Replicare Ultra 66000434 SN</td>
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DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note
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<tr>
<td>4945G</td>
<td>dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>48.49</td>
<td>6.10</td>
<td>Hydrocoll 900744 HR</td>
</tr>
<tr>
<td>4946H</td>
<td>dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>90.25</td>
<td>6.10</td>
<td>Hydrocoll 900936 HR</td>
</tr>
</tbody>
</table>

DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

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<tr>
<td>4897R</td>
<td>dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5</td>
<td>2 1 ..</td>
<td>..</td>
<td>*81.74</td>
<td>6.10</td>
<td>DuoDERM CGF H7660 CC</td>
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<tr>
<td>4920Y</td>
<td>dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5</td>
<td>2 1 ..</td>
<td>..</td>
<td>*222.66</td>
<td>6.10</td>
<td>DuoDERM CGF H7662 CC</td>
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DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

Note
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note
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<tr>
<td>2777F</td>
<td>dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>101.32</td>
<td>6.10</td>
<td>Aquacel Extra 420672 CC</td>
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<tr>
<td>2803M</td>
<td>dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5</td>
<td>2 1 ..</td>
<td>..</td>
<td>*209.04</td>
<td>6.10</td>
<td>Aquacel Extra 420673 CC</td>
</tr>
<tr>
<td>4698G</td>
<td>dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>84.05</td>
<td>6.10</td>
<td>Aquacel 403770 CC</td>
</tr>
</tbody>
</table>

DRESSING HYDROFIBRE GELLING FIBRE

Note
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<tr>
<td>2486W</td>
<td>dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>95.82</td>
<td>6.10</td>
<td>Durafiber 66800560 SN</td>
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<tr>
<td>2445Q</td>
<td>dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5</td>
<td>‡2 1 ..</td>
<td>..</td>
<td>*199.16</td>
<td>6.10</td>
<td>Durafiber 66800561 SN</td>
</tr>
<tr>
<td>2462N</td>
<td>dressing hydrofibre gelling fibre 2 cm x</td>
<td>‡1 1 ..</td>
<td>..</td>
<td>80.04</td>
<td>6.10</td>
<td>Durafiber 66800563 SN</td>
</tr>
</tbody>
</table>
### DRESSING HYDROFIBRE WITH SILVER

**Authority required**

Wound critical colonisation or chronic wounds that have not responded to conventional dressings

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

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<td>10097K</td>
<td>dressing hydrofibre with silver 10 cm x 10 cm dressing, 10</td>
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<td>262.40</td>
<td>6.10</td>
<td>Aquacel Ag 403708 CC</td>
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<tr>
<td>10098L</td>
<td>dressing hydrofibre with silver 15 cm x 15 cm dressing, 5</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>279.45</td>
<td>6.10</td>
<td>Aquacel Ag 403710 CC</td>
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<tr>
<td>10105W</td>
<td>dressing hydrofibre with silver 2 cm x 45 cm rope, 5</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>224.78</td>
<td>6.10</td>
<td>Aquacel Ag 403771 CC</td>
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<tr>
<td>2471C</td>
<td>dressing hydrogel 10 cm x 10 cm dressing, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>114.38</td>
<td>6.10</td>
<td>Sorbact Absorption Dressing 98222 QL</td>
</tr>
<tr>
<td>4912M</td>
<td>dressing hydrogel amorphous gel, 10 x 15 g tubes</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>64.82</td>
<td>6.10</td>
<td>DuoDERM Gel H7990 CC</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Sorbact Absorption Dressing 98222 QL</td>
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<td></td>
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<td>72.43</td>
<td>6.10</td>
<td>Comfeel Purilon Gel 3900 CT</td>
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<tr>
<td>4894N</td>
<td>dressing hydrogel amorphous gel, 25 g</td>
<td>4</td>
<td>3</td>
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<td>*66.56</td>
<td>6.10</td>
<td>Intrasite Gel 7313 SN</td>
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<tr>
<td>4599C</td>
<td>dressing hydrogel amorphous gel, 50 g</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*31.57</td>
<td>6.10</td>
<td>SoloSite Gel 36361338 SN</td>
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<tr>
<td>4913N</td>
<td>dressing hydrogel amorphous gel, 3 x 30 g tubes</td>
<td>3</td>
<td>1</td>
<td>..</td>
<td>*97.45</td>
<td>6.10</td>
<td>DuoDERM Gel H7987 CC</td>
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<tr>
<td>4914P</td>
<td>dressing hydrogel amorphous gel, 50 g</td>
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<td>*33.46</td>
<td>6.10</td>
<td>Solugel 10336 JJ</td>
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<tr>
<td>2533H</td>
<td>dressing hydrogel foam 10 cm x 10 cm dressing, 10</td>
<td>1</td>
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<td>79.79</td>
<td>6.10</td>
<td>Sorbact Foam Dressing 98310 QL</td>
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<td>2512F</td>
<td>dressing hydrogel ribbon 1 cm x 50 cm dressing, 20</td>
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<td>118.23</td>
<td>6.10</td>
<td>Sorbact Ribbon Gauze 598118 QL</td>
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<tr>
<td>2529D</td>
<td>dressing hydrogel ribbon 5 cm x 200 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>114.38</td>
<td>6.10</td>
<td>Sorbact Ribbon Gauze 598120 QL</td>
</tr>
</tbody>
</table>
### DRESSING HYDROGEL SHEET

**Note**
This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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<tr>
<td>4806Y</td>
<td>dressing hydrogel sheet 10 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*53.62</td>
<td>6.10</td>
<td>Aquaclear 900796 HR</td>
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**Note**
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<tbody>
<tr>
<td>4911L</td>
<td>dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*83.54</td>
<td>6.10</td>
<td>Nu-Gel 2497 KI</td>
</tr>
</tbody>
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### DRESSING NON ADHERENT

**Note**
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<tr>
<td>4243H</td>
<td>DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>63.96</td>
<td>6.10</td>
<td>Mepitel 290510 MH</td>
</tr>
<tr>
<td>4244J</td>
<td>DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>107.96</td>
<td>6.10</td>
<td>Mepitel 290710 MH</td>
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<tr>
<td>4861W</td>
<td>dressing non adherent 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>36.03</td>
<td>6.10</td>
<td>Melolin 66974933 SN</td>
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<tr>
<td>4862X</td>
<td>dressing non adherent 10 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*25.44</td>
<td>6.10</td>
<td>Cutilin Non-Stick Wound Pad 36361375 SN</td>
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<tr>
<td>4819P</td>
<td>dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*15.96</td>
<td>6.10</td>
<td>Cutilin Non-Stick Wound Pad 36361374 SN</td>
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<td>4860T</td>
<td>dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*17.24</td>
<td>6.10</td>
<td>Melolin 36361357 SN</td>
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<tr>
<td>4755G</td>
<td>dressing non adherent 5 cm x 7.5 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.36</td>
<td>6.10</td>
<td>Telfa 1970C KE</td>
</tr>
<tr>
<td>4758K</td>
<td>dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.57</td>
<td>6.10</td>
<td>Telfa 2140C KE</td>
</tr>
<tr>
<td>4844Y</td>
<td>dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>12.36</td>
<td>6.10</td>
<td>Telfa 7650C KE</td>
</tr>
</tbody>
</table>

**Note**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4944F</td>
<td>dressing non adherent 7.5 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>15.58</td>
<td>6.10</td>
<td>Atrauman 499513 HR</td>
</tr>
</tbody>
</table>

### DRESSING TULLE NON GAUZE PARAFFIN
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispersed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4909J</td>
<td>dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1</td>
<td>10</td>
<td>1</td>
<td>*16.06</td>
<td>6.10</td>
<td>Adaptic 2012 KI</td>
</tr>
</tbody>
</table>

**Dressing with Silver**

**Authority Required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

**Note**

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispersed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4646M</td>
<td>dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings</td>
<td>‡1</td>
<td>..</td>
<td>176.22</td>
<td>6.10</td>
<td>Biatain Ag 9622 CT</td>
</tr>
<tr>
<td>4647N</td>
<td>dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings</td>
<td>‡1</td>
<td>..</td>
<td>191.63</td>
<td>6.10</td>
<td>Biatain Ag 9632 CT</td>
</tr>
</tbody>
</table>

**Dressing with Silver**

**Authority Required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

**Note**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4648P</td>
<td>dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings</td>
<td>‡1</td>
<td>..</td>
<td>44.12</td>
<td>6.10</td>
<td>Atrauman Ag 499572 HR</td>
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</tbody>
</table>

**Gauze and Cotton Tissue Combine Roll**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispersed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4761N</td>
<td>gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>17.55</td>
<td>6.10</td>
<td>JJ 12010 JJ</td>
</tr>
</tbody>
</table>

**Gauze and Cotton Tissue Combine Roll**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4767X</td>
<td>gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>11.92</td>
<td>6.10</td>
<td>BSN 2902165 BV</td>
</tr>
</tbody>
</table>

**Tape Non Woven Retention Polyacrylate**

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4917T</td>
<td>tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>11.38</td>
<td>6.10</td>
<td>Mefix 310250 MH</td>
</tr>
</tbody>
</table>

**Tape Non Woven Retention Polyacrylate**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<th>Code</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4915Q</td>
<td>tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>13.21</td>
<td>6.10</td>
<td>Medipore 2961 MM</td>
</tr>
</tbody>
</table>

**Tape Plaster Adhesive Elastic**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<tr>
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<tbody>
<tr>
<td>4780N</td>
<td>tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>13.95</td>
<td>6.10</td>
<td>Leukoplast 01071-00 BV</td>
</tr>
<tr>
<td>4781P</td>
<td>tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>20.50</td>
<td>6.10</td>
<td>Leukoplast 01072-00 BV</td>
</tr>
<tr>
<td>4782Q</td>
<td>tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>24.55</td>
<td>6.10</td>
<td>Leukoplast 01073-00 BV</td>
</tr>
</tbody>
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**Tape Plaster Adhesive Hypoallergenic**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS...
<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4783R</td>
<td>tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>11.10</td>
<td>6.10</td>
<td>Leukopor 2471 BV</td>
</tr>
<tr>
<td>4785W</td>
<td>tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>11.42</td>
<td>6.10</td>
<td>Leukosilk 1021 BV</td>
</tr>
<tr>
<td>4787Y</td>
<td>tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>14.34</td>
<td>6.10</td>
<td>Leukosilk 1022 BV</td>
</tr>
<tr>
<td>4794H</td>
<td>tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>13.76</td>
<td>6.10</td>
<td>Leukopor 2472 BV</td>
</tr>
<tr>
<td>4788B</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>17.55</td>
<td>6.10</td>
<td>Leukoflex 1124 BV</td>
</tr>
<tr>
<td>4789C</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>18.55</td>
<td>6.10</td>
<td>Leukosilk 1024 BV</td>
</tr>
<tr>
<td>4790D</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>17.63</td>
<td>6.10</td>
<td>Leukopor 2474 BV</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE HYPOALLERGENIC**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4848E</td>
<td>tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>11.39</td>
<td>6.10</td>
<td>Nexcare Durable Cloth First Aid Tape 799 MM</td>
</tr>
<tr>
<td>4849F</td>
<td>tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>11.39</td>
<td>6.10</td>
<td>Nexcare Gentle Paper First Aid Tape 789 MM</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE WITH SILICONE**

*Note*
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4239D</td>
<td>tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>21.71</td>
<td>6.10</td>
<td>Mepitac 298300 MH</td>
</tr>
<tr>
<td>4240E</td>
<td>tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>21.71</td>
<td>6.10</td>
<td>Mepitac 298400 MH</td>
</tr>
</tbody>
</table>

agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.
NOTE—

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 1 of the Schedule.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Form/Strength</th>
<th>Pack and Price</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10031Y</td>
<td>alprostadil 10 microgram injection [1 x 10 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1@ 16.51</td>
<td>PF</td>
</tr>
<tr>
<td>10030X</td>
<td>alprostadil 20 microgram injection [1 x 20 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1@ 21.07</td>
<td>PF</td>
</tr>
<tr>
<td>4118R</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1</td>
<td>1@ 8.11</td>
<td>JT</td>
</tr>
<tr>
<td>4453J</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100</td>
<td>100@ 19.85</td>
<td>JT</td>
</tr>
<tr>
<td>4657D</td>
<td>bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage</td>
<td>1@ 14.43</td>
<td>MH</td>
</tr>
<tr>
<td>4748X</td>
<td>bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage</td>
<td>1@ 29.24</td>
<td>BV</td>
</tr>
<tr>
<td>4748X</td>
<td>bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage</td>
<td>1@ 13.30</td>
<td>CC</td>
</tr>
<tr>
<td>4654V</td>
<td>BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1</td>
<td>1@ 13.87</td>
<td>BV</td>
</tr>
<tr>
<td>4598B</td>
<td>bandage compression bandage: four layer, 1 bandage</td>
<td>1@ 30.65</td>
<td>SN</td>
</tr>
<tr>
<td>4598E</td>
<td></td>
<td>1@ 45.52</td>
<td>SN</td>
</tr>
<tr>
<td>4813H</td>
<td>bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1</td>
<td>1@ 7.33</td>
<td>MM</td>
</tr>
<tr>
<td>4660G</td>
<td>bandage retention cohesive heavy 10 cm x 2 m bandage, 1</td>
<td>1@ 6.47</td>
<td>MM</td>
</tr>
<tr>
<td>4814J</td>
<td>bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1</td>
<td>1@ 10.88</td>
<td>MM</td>
</tr>
<tr>
<td>4811F</td>
<td>bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1</td>
<td>1@ 3.80</td>
<td>MM</td>
</tr>
<tr>
<td>4812G</td>
<td>bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1</td>
<td>1@ 5.44</td>
<td>MM</td>
</tr>
<tr>
<td>4662J</td>
<td>bandage retention cohesive light 10 cm x 2 m bandage</td>
<td>1@ 12.33</td>
<td>BV</td>
</tr>
<tr>
<td>4719J</td>
<td>bandage retention cohesive light 6 cm x 2 m bandage</td>
<td>1@ 4.69</td>
<td>BV</td>
</tr>
<tr>
<td>4729X</td>
<td>bandage retention cotton crepe 10 cm x 2.3 m bandage</td>
<td>1@ 12.08</td>
<td>BV</td>
</tr>
<tr>
<td>4729X</td>
<td>bandage retention cotton crepe 10 cm x 2.3 m bandage</td>
<td>1@ 9.48</td>
<td>KE</td>
</tr>
<tr>
<td>4727T</td>
<td>bandage retention cotton crepe 5 cm x 2.3 m bandage</td>
<td>1@ 5.50</td>
<td>KE</td>
</tr>
<tr>
<td>4727T</td>
<td>bandage retention cotton crepe 5 cm x 2.3 m bandage</td>
<td>1@ 6.73</td>
<td>BV</td>
</tr>
<tr>
<td>4728W</td>
<td>bandage retention cotton crepe 7.5 cm x 2.3 m bandage</td>
<td>1@ 9.23</td>
<td>BV</td>
</tr>
<tr>
<td>4728W</td>
<td>bandage retention cotton crepe 7.5 cm x 2.3 m bandage</td>
<td>1@ 7.90</td>
<td>KE</td>
</tr>
<tr>
<td>4799N</td>
<td>bandage tubular long stocking bandage: large size, 1 bandage</td>
<td>1@ 15.35</td>
<td>MH</td>
</tr>
<tr>
<td>4797L</td>
<td>bandage tubular long stocking bandage: medium size, 1 bandage</td>
<td>1@ 15.35</td>
<td>MH</td>
</tr>
<tr>
<td>4674B</td>
<td>bandage tubular long stocking bandage: small size, 1 bandage</td>
<td>1@ 15.35</td>
<td>MH</td>
</tr>
<tr>
<td>4675C</td>
<td>bandage tubular long stocking bandage: XX/large size, 1 bandage</td>
<td>1@ 15.36</td>
<td>MH</td>
</tr>
<tr>
<td>4816L</td>
<td>bandage tubular short stocking bandage: large D/E size, 1 bandage</td>
<td>1@ 9.48</td>
<td>MH</td>
</tr>
<tr>
<td>4815K</td>
<td>bandage tubular short stocking bandage: medium C/D size, 1 bandage</td>
<td>1@ 9.48</td>
<td>MH</td>
</tr>
<tr>
<td>4661H</td>
<td>bandage tubular short stocking bandage: small B/C size, 1 bandage</td>
<td>1@ 9.48</td>
<td>MH</td>
</tr>
<tr>
<td>4670T</td>
<td>bandage zinc paste 10 cm x 9.1 m bandage, 1</td>
<td>1@ 11.18</td>
<td>CC</td>
</tr>
<tr>
<td>4669R</td>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>1@ 11.62</td>
<td>MH</td>
</tr>
<tr>
<td>4750B</td>
<td></td>
<td>1@ 36.18</td>
<td>SN</td>
</tr>
<tr>
<td>4150K</td>
<td>bromazepam 3 mg tablet, 30</td>
<td>30@ 11.53</td>
<td>RO</td>
</tr>
<tr>
<td>4151L</td>
<td>bromazepam 6 mg tablet, 30</td>
<td>30@ 14.04</td>
<td>RO</td>
</tr>
<tr>
<td>4055X</td>
<td>calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4094L</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>60@ 5.62</td>
<td>IA, PP</td>
</tr>
<tr>
<td>4323C</td>
<td></td>
<td>60@ 5.62</td>
<td>IA, PP</td>
</tr>
<tr>
<td>4142B</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
<td>120@ 7.89</td>
<td>PP</td>
</tr>
<tr>
<td>4681J</td>
<td>dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1</td>
<td>1@ 9.45</td>
<td>KI</td>
</tr>
<tr>
<td>4832H</td>
<td>DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1</td>
<td>1@ 10.27</td>
<td>UM</td>
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<tr>
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The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Department of Human Services on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.
<table>
<thead>
<tr>
<th>Premium Priced Brand</th>
<th>Form and Strength</th>
<th>Therapeutic Group Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teveten</td>
<td>eprosartan 400 mg tablet, 28</td>
<td>3.50</td>
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<tr>
<td>Teveten</td>
<td>eprosartan 600 mg tablet, 28</td>
<td>3.50</td>
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<tr>
<td>Olmetec</td>
<td>olmesartan medoxomil 20 mg tablet, 30</td>
<td>2.51</td>
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<tr>
<td>Olmetec</td>
<td>olmesartan medoxomil 40 mg tablet, 30</td>
<td>2.51</td>
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</tbody>
</table>

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, losartan and valsartan.
BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM
1 April 2015

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product. Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescribers forms supplied by Department of Human Services contain a box to be ticked where brand substitution is not to take place. Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.
<table>
<thead>
<tr>
<th>Brand Premium</th>
<th>Max. Qty</th>
<th>Benchmark Priced Brands</th>
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</thead>
<tbody>
<tr>
<td><strong>Brand Premium</strong></td>
<td><strong>Form and Strength</strong></td>
<td><strong>Premium Priced</strong></td>
</tr>
<tr>
<td><strong>Abccoin-V</strong></td>
<td>phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL</td>
<td>1.90</td>
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<tr>
<td>Accupril</td>
<td>quinapril 10 mg tablet, 30</td>
<td>1.30</td>
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<td></td>
<td>quinapril 20 mg tablet, 30</td>
<td>1.30</td>
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<tr>
<td></td>
<td>quinapril 5 mg tablet, 30</td>
<td>1.30</td>
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<tr>
<td>Actilax</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>0.89</td>
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<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>2.67</td>
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<td>Adalat 10</td>
<td>nifedipine 10 mg tablet, 60</td>
<td>1.84</td>
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<td>nifedipine 20 mg tablet, 60</td>
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<tr>
<td>Adalat Oros 30</td>
<td>nifedipine 30 mg tablet: modified release, 30 tablets</td>
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<td>nifedipine 60 mg tablet: modified release, 30 tablets</td>
<td>2.99</td>
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<td>Aldactone</td>
<td>spironolactone 100 mg tablet, 100</td>
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<td>spironolactone 25 mg tablet, 100</td>
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<td>Aldomet</td>
<td>methyl dopa 250 mg tablet, 100</td>
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<td>Alphagan</td>
<td>brimonidine tartrate 0.2% eye drops, 5 mL</td>
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<td>Amaryl</td>
<td>glimepiride 1 mg tablet, 30</td>
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<td>glimepiride 2 mg tablet, 30</td>
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<tr>
<td></td>
<td>glimepiride 4 mg tablet, 30</td>
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<td>Amaryl</td>
<td>amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>Amoxil</td>
<td>amoxicillin 250 mg capsule, 20</td>
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<td>amoxicillin 500 mg capsule, 20</td>
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<tr>
<td>Amoxil Forte</td>
<td>amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>Anafranil 25</td>
<td>clomipramine hydrochloride 25 mg tablet, 50</td>
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<td>Anaprox 550</td>
<td>naproxen sodium 550 mg tablet, 50</td>
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<td>Androcur</td>
<td>cyproterone acetate 50 mg tablet, 20</td>
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<td>cyproterone acetate 100 mg tablet, 50</td>
<td>1.88</td>
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<td>Anginine Stabilised</td>
<td>glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets</td>
<td>2.94</td>
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<td>triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g</td>
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<td>triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g</td>
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<td>Aropax</td>
<td>paroxetine 20 mg tablet, 30</td>
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<td>Astrix</td>
<td>aspirin 100 mg tablet, 112</td>
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<td>candesartan cilexetil 16 mg tablet, 30</td>
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<tr>
<td>candesartan cilexetil 32 mg tablet, 30</td>
<td>1.57</td>
<td>Adesan; APO-Candesartan; Auro-Candesartan 32; Candesartan AN; Candesartan Aspen 32; Candesartan GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmaco Candesartan 32; Terry White Chemists Candesartan</td>
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<td>candesartan cilexetil 4 mg tablet, 30</td>
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<td>Adesan; APO-Candesartan; Auro-Candesartan 4; Candesartan AN; Candesartan Aspen 4; Candesartan GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmaco Candesartan 4; Terry White Chemists Candesartan</td>
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<tr>
<td>Premium Priced Brand</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>candesartan cilexetil 8 mg tablet, 30</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>amoxyclavin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>amoxyclavin 500 mg + clavulanic acid 125 mg tablet, 10</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>amoxyclavin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>amoxyclavin 875 mg + clavulanic acid 125 mg tablet, 10</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>moclobemide 150 mg tablet, 60</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>moclobemide 300 mg tablet, 60</td>
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<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>mirtazapine 30 mg tablet, 30</td>
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<td>mirtazapine 45 mg tablet, 30</td>
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<td>MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30</td>
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<td>MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30</td>
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<td>brinzolamide 1% eye drops, 5 mL</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>METPROLOL TARTRATE Tablet 100 mg, 60</td>
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<tr>
<td>Metoprolol Tartrate Tablet 100 mg, 60</td>
<td>METPROLOL TARTRATE Tablet 50 mg, 100</td>
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</tr>
<tr>
<td>Form and Strength</td>
<td>Max. Qty</td>
<td>Brand Premium</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>----------</td>
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<tr>
<td>betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g</td>
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<tr>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
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<tr>
<td>betaxolol 0.5% eye drops, 5 mL</td>
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<tr>
<td>bisoprolol fumarate 10 mg tablet, 28</td>
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<td>bisoprolol fumarate 2.5 mg tablet, 28</td>
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<tr>
<td>ethinyl oestra diol 35 microgram + norethisterone 500 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
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<td>captopril 25 mg tablet, 90</td>
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<tr>
<td>captopril 50 mg tablet, 90</td>
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<td>3.46</td>
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<td>succinate 1 g tablet, 120</td>
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<td>cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL</td>
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<tr>
<td>cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL</td>
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<td>cefaclor 375 mg tablet: modified release, 10</td>
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<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
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<tr>
<td>carmelllose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
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<td>4.77</td>
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<td>carmelllose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
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<tr>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
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<td>citalopram 20 mg tablet, 28</td>
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<td>ciprofloxacin 250 mg tablet, 14</td>
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<td>ciprofloxacin 500 mg tablet, 14</td>
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<td>ciprofloxacin 750 mg tablet, 14</td>
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<td>colchicine 500 microgram tablet, 30</td>
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<td>perindopril arginine 2.5 mg tablet, 30 x 0.4 mL unit doses</td>
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<td>clindamycin 150 mg capsule, 24</td>
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<td>glibenclamide 5 mg tablet, 100</td>
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<td>methylprednisolone acetate 40 mg/mL injection, 5 x 1 ml vials</td>
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<td>medroxypregesterone acetate 150 mg/mL injection, 1 x 1 ml vial</td>
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<td>metformin hydrochloride 500 mg tablet, 100</td>
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<td>metformin hydrochloride 1 g tablet, 90</td>
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<td>metformin hydrochloride 850 mg tablet, 60</td>
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<tr>
<td>Premium Priced Brand</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
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<td>Diabex XR</td>
<td>metformin hydrochloride 500 mg tablet: modified release, 120 tablets</td>
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<td>Diabex XR 1000</td>
<td>metformin hydrochloride 1 g tablet: modified release, 60 tablets</td>
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<td>Diamicon 60mg MR</td>
<td>gliclazide 60 mg tablet: modified release, 60 tablets</td>
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<td>Diprosone</td>
<td>betamethasone (as dipropionate) 0.05% cream, 15 g</td>
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<td>betamethasone (as dipropionate) 0.05% ointment, 15 g</td>
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<td>Doryx</td>
<td>doxycycline 100 mg capsule: modified release, 21 capsules</td>
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<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
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<td>doxycycline 100 mg capsule: modified release, 50 capsules</td>
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<td>Dulcolax</td>
<td>bisacodyl 10 mg suppository, 10</td>
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<td>Dulose</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL</td>
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<td>LACTULOSE Mixture 3.43 g per 5 mL, 500 mL</td>
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<td>Duratears</td>
<td>paraffin 1 g/eye ointment, 3.5 g</td>
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<td>E.E.S. 200</td>
<td>erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>E.E.S. 400 Filtab</td>
<td>erythromycin (as ethylsuccinate) 400 mg tablet, 25</td>
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<td>E.E.S. Granules</td>
<td>erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>Elocon</td>
<td>mometasone furoate 0.1% (1 mg/g) cream, 15 g</td>
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<td>mometasone furoate 0.1% lotion, 30 mL</td>
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<td>Epilim EC</td>
<td>valproate sodium 200 mg tablet: enteric, 100</td>
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<td>valproate sodium 500 mg tablet: enteric, 100</td>
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<td>Eryc</td>
<td>erythromycin 250 mg capsule: enteric, 25</td>
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<td>Fasigyn</td>
<td>tinidazole 500 mg tablet, 4</td>
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<td>Feldene</td>
<td>piroxicam 10 mg capsule, 50</td>
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<td>piroxicam 20 mg capsule, 25</td>
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<td>Feldene-D Flagyl</td>
<td>piroxicam 20 mg tablet: dispersible, 25</td>
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<td>metronidazole 200 mg tablet, 21</td>
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<td>metronidazole 400 mg tablet, 21</td>
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<td>Fosamax Plus 70 mg/140 mcg</td>
<td>alendronate 70 mg + cocaecaliferol 140 microgram tablet, 4</td>
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<td>Genteal</td>
<td>HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1</td>
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<td>Genteal gel</td>
<td>hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g</td>
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<td>Glucophage</td>
<td>metformin hydrochloride 850 mg tablet, 60</td>
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<td>Gopten</td>
<td>trandolapril 1 mg capsule, 28</td>
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<td>trandolapril 2 mg capsule, 28</td>
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<td></td>
<td>trandolapril 4 mg capsule, 28</td>
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<td>trandolapril 500 microgram capsule, 28</td>
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<td>Imdur 120 mg</td>
<td>isosorbide mononitrate 120 mg tablet: modified release, 30 tablets</td>
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<td>Imdur Durule</td>
<td>isosorbide mononitrate 60 mg tablet: modified release, 30 tablets</td>
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<td>Imigran</td>
<td>SUMATRIPTAN Tablet 50 mg (as succinate), 2</td>
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<td>Premium Priced Brand</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
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<tr>
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<td>Imodium</td>
<td>loperamide hydrochloride 2 mg capsule, 12</td>
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<td>Indocid</td>
<td>indomethacin 25 mg capsule, 50</td>
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<td>Isotin</td>
<td>verapamil hydrochloride 80 mg tablet, 100</td>
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<td>Isotin 180 SR</td>
<td>verapamil hydrochloride 180 mg tablet: modified release, 30 tablets</td>
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<td>Isotin SR</td>
<td>verapamil hydrochloride 240 mg tablet: modified release, 30 tablets</td>
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<td>Keflex</td>
<td>cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>cephalexin 250 mg capsule, 20</td>
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<td>cephalexin 250 mg capsule, 20</td>
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<td>cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>cephalexin 500 mg capsule, 20</td>
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<tr>
<td>Kenacomb Otic</td>
<td>triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL</td>
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<tr>
<td>Klacid</td>
<td>clarithromycin 250 mg tablet, 14</td>
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<td>Lamictal</td>
<td>lamotrigine 100 mg tablet, 56</td>
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<td>lamotrigine 200 mg tablet, 56</td>
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<td>lamotrigine 25 mg tablet, 56</td>
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<td>lamotrigine 5 mg tablet, 56</td>
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<td>lamotrigine 50 mg tablet, 56</td>
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<td>Lanoxin</td>
<td>digoxin 250 microgram tablet, 100</td>
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<td>Lanoxin-PG</td>
<td>digoxin 62.5 microgram tablet, 200</td>
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<td>Lasix</td>
<td>frusemide 40 mg tablet, 100</td>
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<td>Lasix-M</td>
<td>frusemide 20 mg tablet, 50</td>
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<td>Lexapro</td>
<td>escitalopram 10 mg tablet, 28</td>
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<tr>
<td>Lipex 10</td>
<td>simvastatin 10 mg tablet, 30</td>
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<tr>
<td>Lipex 20</td>
<td>simvastatin 20 mg tablet, 30</td>
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<td>Brand Premium</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
</tr>
<tr>
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<tr>
<td><strong>Lipex 40</strong></td>
<td>simvastatin 40 mg tablet, 30</td>
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<td><strong>Lipex 80</strong></td>
<td>simvastatin 80 mg tablet, 30</td>
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<tr>
<td><strong>Liquifilm Tears</strong></td>
<td>polyvinyl alcohol 1.4% eye drops, 15 mL</td>
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<tr>
<td><strong>Lomotil</strong></td>
<td>diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20</td>
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<tr>
<td><strong>Lopresor 100</strong></td>
<td>METOPROLOL TARTRATE Tablet 100 mg, 60</td>
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<tr>
<td><strong>Lopresor 50</strong></td>
<td>METOPROLOL TARTRATE Tablet 50 mg, 100</td>
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<td><strong>Losec Tablets</strong></td>
<td>omeprazole 20 mg tablet: enteric, 30 tablets</td>
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<td><strong>Luvox</strong></td>
<td>fluvoxamine maleate 100 mg tablet, 30</td>
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<td><strong>Maxamox</strong></td>
<td>amoxicillin 1 g tablet, 14</td>
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<td><strong>Maxolon</strong></td>
<td>metoclopramide hydrochloride 10 mg tablet, 25</td>
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<td><strong>Mayne Pharma Doxycycline</strong></td>
<td>doxycycline 100 mg capsule: modified release, 21 capsules</td>
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<tr>
<td><strong>Microgynon 30 ED</strong></td>
<td>ethinylöestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&amp;) inert substance tablet [28], [112] [4 x 28]</td>
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<td><strong>Minidib</strong></td>
<td>glipizide 5 mg tablet, 100</td>
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<td><strong>Minomycin-50</strong></td>
<td>minocycline 50 mg tablet, 60</td>
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<td><strong>Mobic</strong></td>
<td>meloxicam 15 mg capsule, 30</td>
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<td>meloxicam 15 mg tablet, 30</td>
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<td>meloxicam 7.5 mg capsule, 30</td>
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<td>meloxicam 7.5 mg tablet, 30</td>
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<td><strong>Mogadon</strong></td>
<td>nitrazepam 5 mg tablet, 25</td>
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<td><strong>Monodur 60 mg</strong></td>
<td>isosorbide mononitrate 60 mg tablet: modified release, 30 tablets</td>
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<tr>
<td><strong>Naprosyn</strong></td>
<td>naproxen 250 mg tablet, 50</td>
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<td><strong>Naprosyn 1 g tablet: modified release, 28</strong></td>
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<td><strong>Naprosyn SR1000</strong></td>
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<td><strong>Naprosyn SR750</strong></td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
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<td><strong>Natrilix</strong></td>
<td>indapamide hemihydrate 2.5 mg tablet, 90</td>
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<td><strong>Nilstat</strong></td>
<td>nystatin 100 000 international units/mL oral liquid, 24 mL</td>
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<td>ethinyleoestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&amp;) inert substance tablet</td>
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<td>Brand Premium</td>
<td>Form and Strength</td>
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<td>Norvasc</td>
<td>temazepam 10 mg tablet, 25</td>
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<td>amlodipine 10 mg tablet, 30</td>
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<td>amlodipine 5 mg tablet, 30</td>
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<td>Oroxine</td>
<td>thyroxine sodium 100 microgram tablet, 200</td>
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<td>thyroxine sodium 75 microgram tablet, 200</td>
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<td>Orudis SR 200</td>
<td>ketoprofen 200 mg capsule: modified release, 28 capsules</td>
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<td>Panadeine Forte</td>
<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
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<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
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<td>Panadol Osteo</td>
<td>paracetamol 665 mg tablet: modified release, 96 tablets</td>
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<td>Panaforcort</td>
<td>prednisone 1 mg tablet, 100</td>
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<td>Panaforcortelone</td>
<td>prednisolone 1 mg tablet, 100</td>
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<td>Plendil ER</td>
<td>felodipine 10 mg tablet: modified release, 30 tablets</td>
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<td>felodipine 2.5 mg tablet: modified release, 30 tablets</td>
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<td>Pravachol</td>
<td>pravastatin sodium 10 mg tablet, 30</td>
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<td>pravastatin sodium 20 mg tablet, 30</td>
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<td>PREXUM 2.5</td>
<td>perindopril arginine 2.5 mg tablet, 30</td>
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<td>Prinivil 10</td>
<td>lisinopril 10 mg tablet, 30</td>
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<td>Prinivil 20</td>
<td>lisinopril 20 mg tablet, 30</td>
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<td>Provera</td>
<td>medroxyprogesterone acetate 10 mg tablet, 100</td>
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<td>medroxyprogesterone acetate 5 mg tablet, 56</td>
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<td>Prozac 20</td>
<td>fluoxetine 20 mg capsule, 28</td>
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<td>Prozac Tab Redipred</td>
<td>fluoxetine 20 mg tablet: dispersible, 28</td>
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<tr>
<td>Refresh Night Time</td>
<td>paraffin 1 g/g eye ointment, 2 x 3.5 g tubes</td>
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<tr>
<td>Brand Premium</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
</tr>
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<td>Rulide</td>
<td>roxithromycin 150 mg tablet, 10</td>
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<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
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<td>Septrin Forte</td>
<td>trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10</td>
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<td>Serepax</td>
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<td>levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100</td>
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<td>Tears Naturale</td>
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<td>dextran-70 0.1% + hyprommellose 0.3% eye drops, 15 mL</td>
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<td>mianserin hydrochloride 10 mg tablet, 50</td>
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<td>Trandate</td>
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<td>Valium</td>
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<td>salbutamol 100 microgram/actuation inhalation: pressurised, 200</td>
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<td>carbomer-980 0.2% eye gel, 10 g</td>
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